US009271819B2

(12) **United States Patent**
Liddicoat et al.

(10) **Patent No.: US 9,271,819 B2**
(45) **Date of Patent: Mar. 1, 2016**

(54) **APPARATUS AND METHOD FOR THE LIGATION OF TISSUE**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 1145 days.

(21) Appl. No.: **12/124,023**

(22) Filed: **May 20, 2008**

(65) **Prior Publication Data**

US 2008/0221593 A1 Sep. 11, 2008

Related U.S. Application Data

(63) Continuation of application No. 10/963,371, filed on Oct. 11, 2004, now Pat. No. 7,846,168.

(60) Provisional application No. 60/510,100, filed on Oct. 9, 2003, provisional application No. 60/528,995, filed on Dec. 12, 2003.

(51) **Int. Cl.**
A61F 2/01 (2006.01)
A61B 17/12 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC ***A61F 2/013*** (2013.01); ***A61B 17/12009*** (2013.01); *A61B 17/12013* (2013.01);
(Continued)

(58) **Field of Classification Search**
CPC A61B 17/12009; A61B 17/12013; A61B 17/12027; A61B 17/12031; A61B 17/12036; A61B 17/1204; A61B 17/0057; A61B 2017/00575; A61B 2017/00243; A61B 2017/00876; A61B 2017/12018; A61B 17/32056; A61B 17/221; A61F 2/013; A61F 2/02; A61F 2002/011; A61F 2002/016
USPC 606/41, 139, 49, 32, 34, 200, 191, 194, 606/148, 157, 110–115, 127, 128, 213, 151, 606/144, 198, 192; 604/104, 106, 107, 508, 604/95.04, 500, 524, 526, 22, 115; 607/5, 607/122, 126, 9; 128/887
See application file for complete search history.

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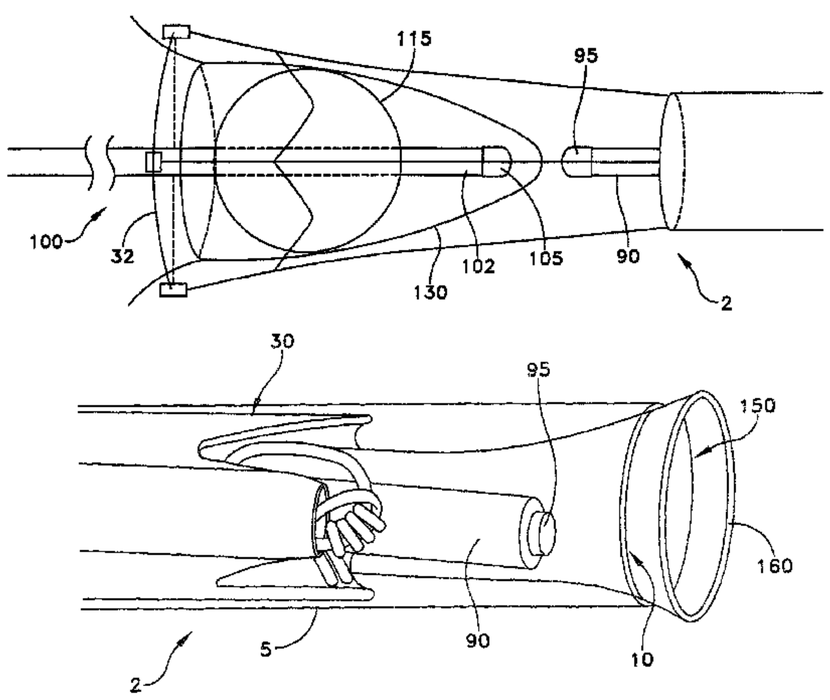
(57) **ABSTRACT**

A novel catheter-based system which ligates the left atrial appendage (LAA) on the outside of the heart, preferably using a combination of catheters and/or instruments, e.g., a guide catheter positioned inside the left atrial appendage which may assist in locating the left atrial appendage and/or assist in the optimal placement of a ligature on the outside of the appendage, and a ligating catheter and/or instrument outside the heart in the pericardial space to set a ligating element at the neck of the left atrial appendage.

12 Claims, 32 Drawing Sheets



(51) **Int. Cl.**
A61B 17/00 (2006.01)
A61B 19/00 (2006.01)

(52) **U.S. Cl.**
CPC *A61B2017/00243* (2013.01); *A61B 2017/00876* (2013.01); *A61B 2019/4857* (2013.01); *A61F 2230/005* (2013.01); *A61F 2230/0006* (2013.01)

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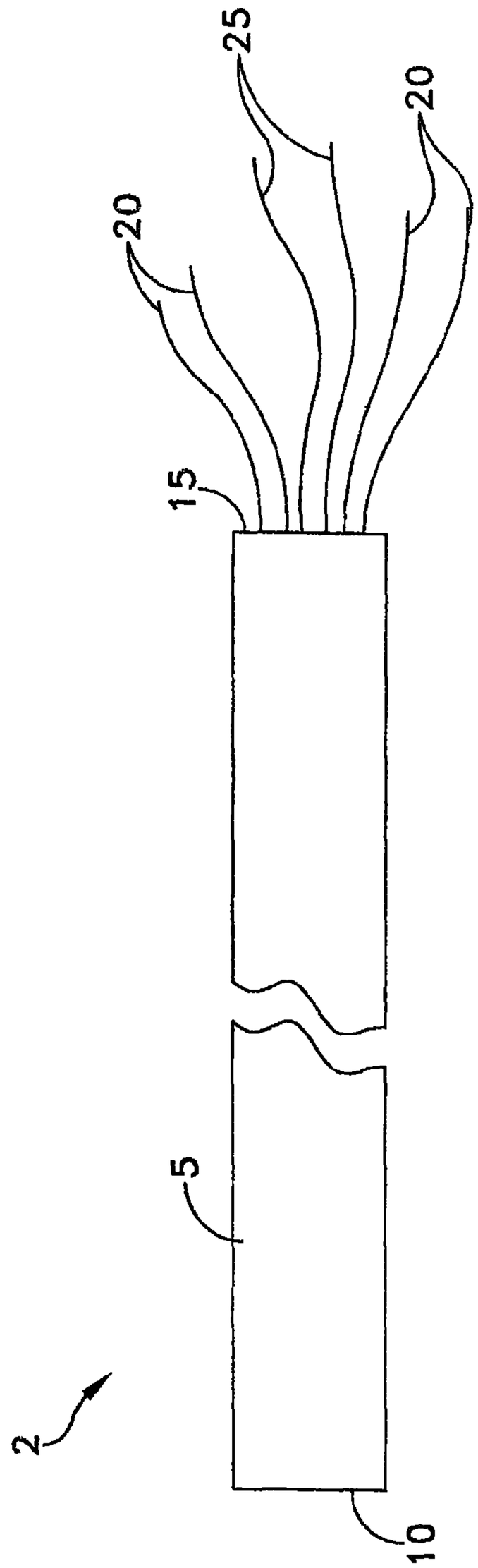


FIG. 1

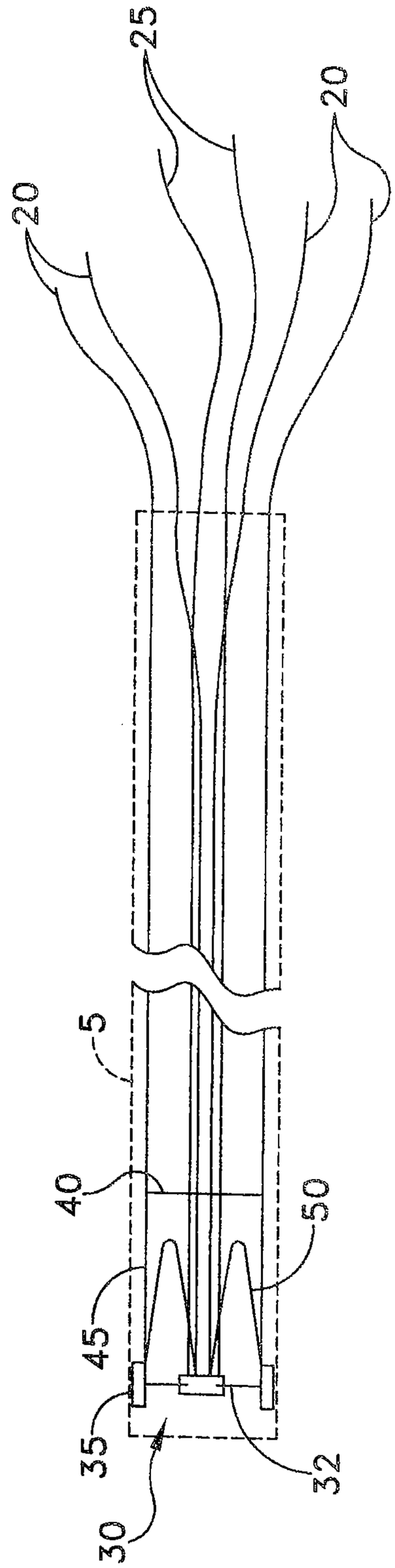


FIG. 2

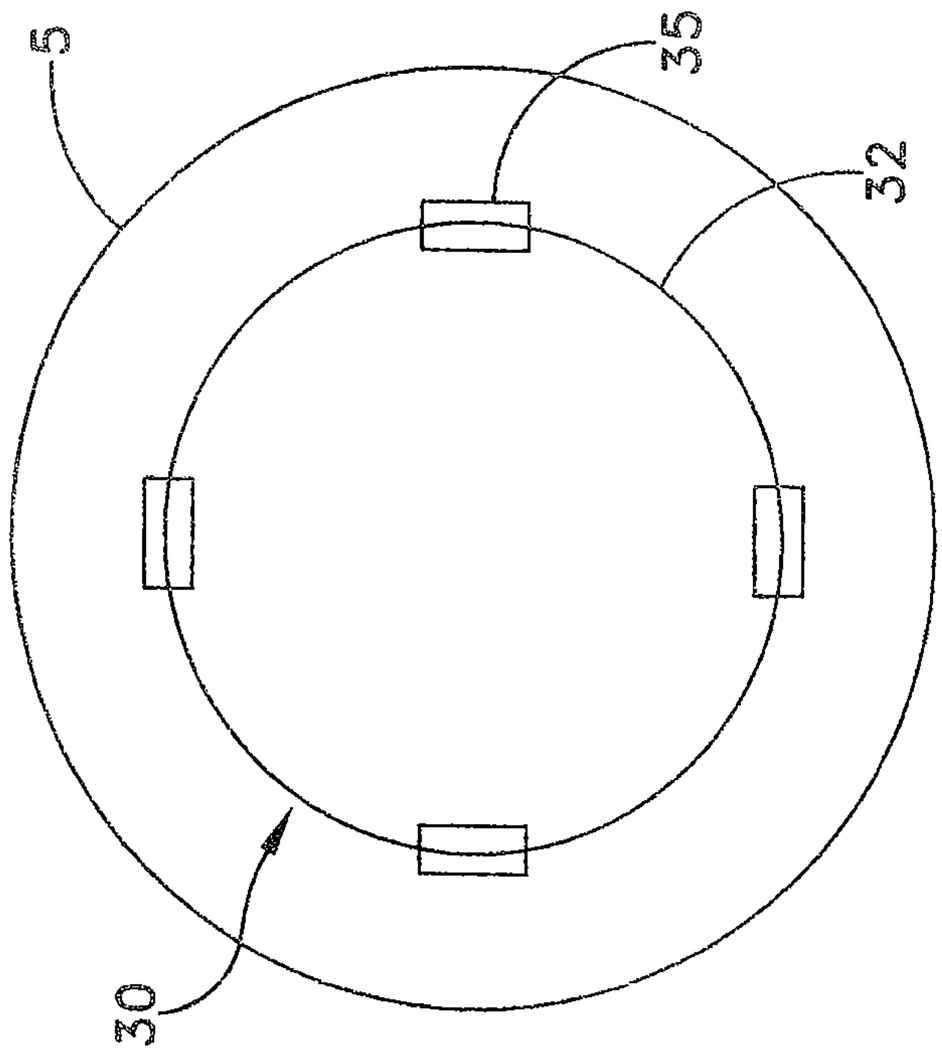


FIG. 3

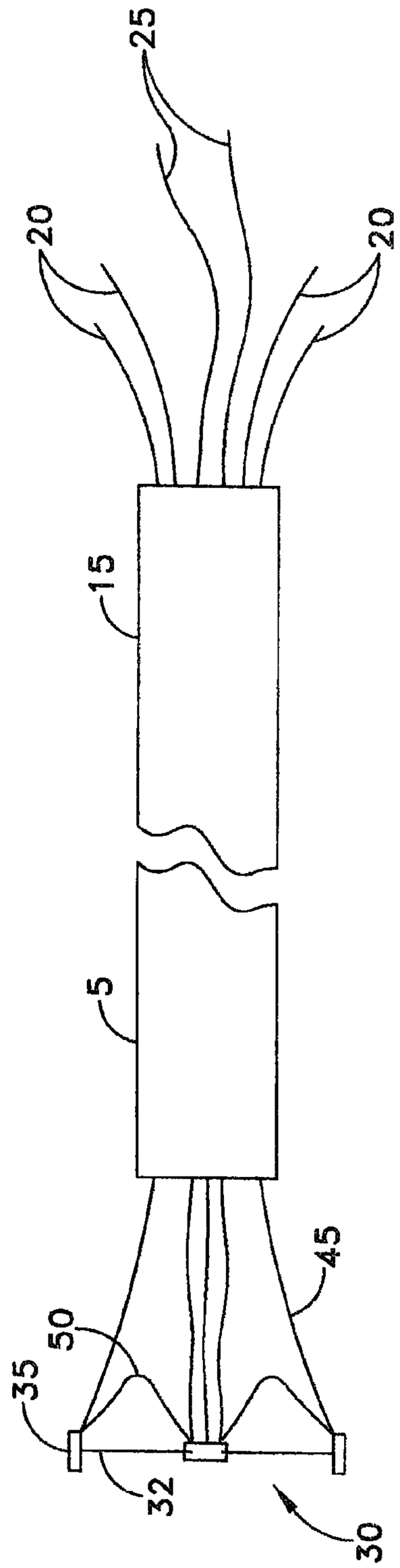


FIG. 4

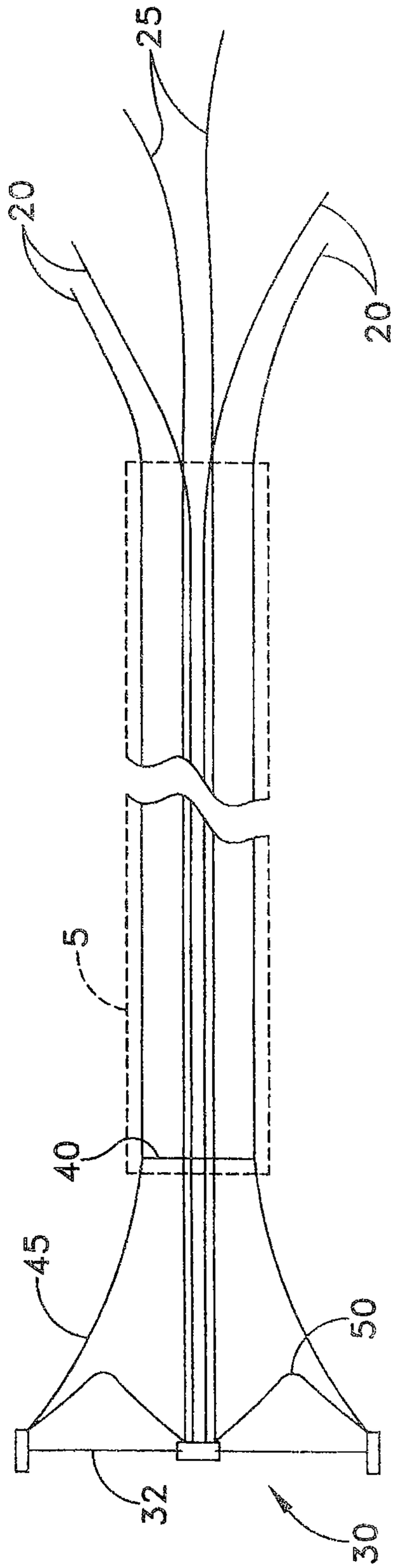


FIG. 5

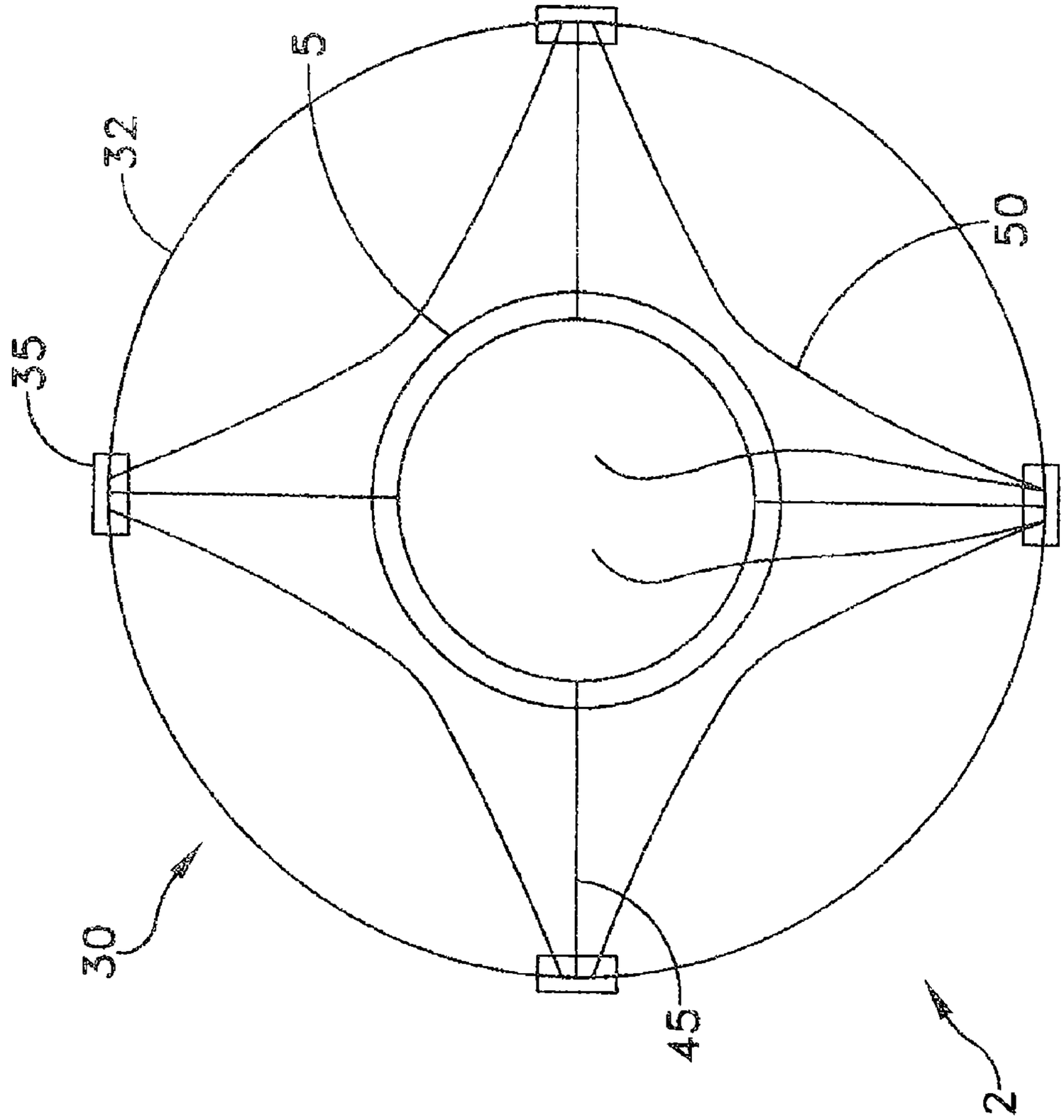


FIG. 6

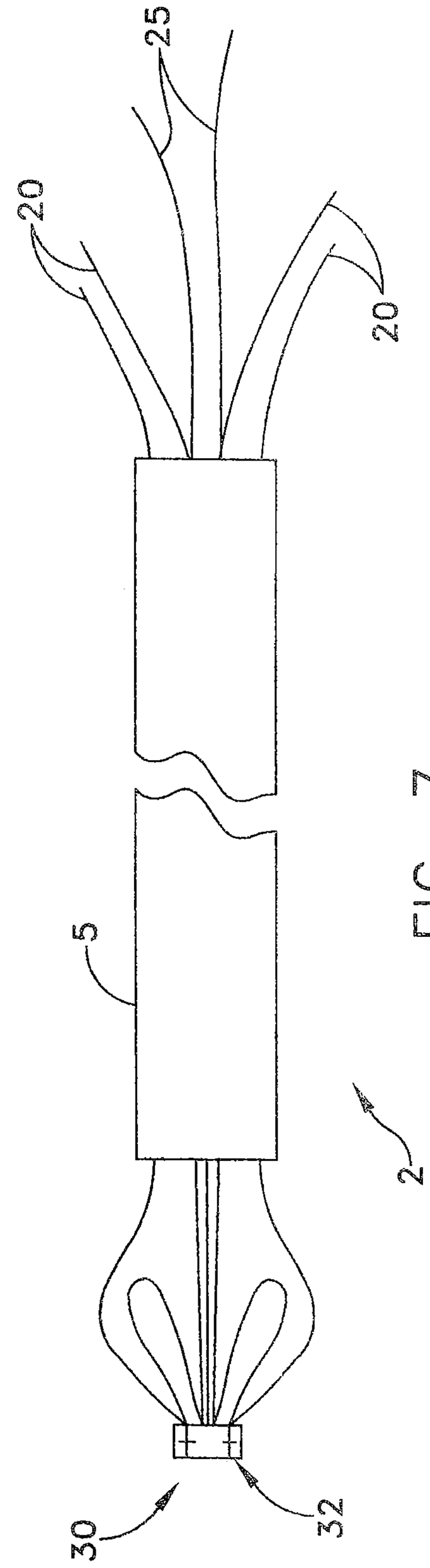


FIG. 7

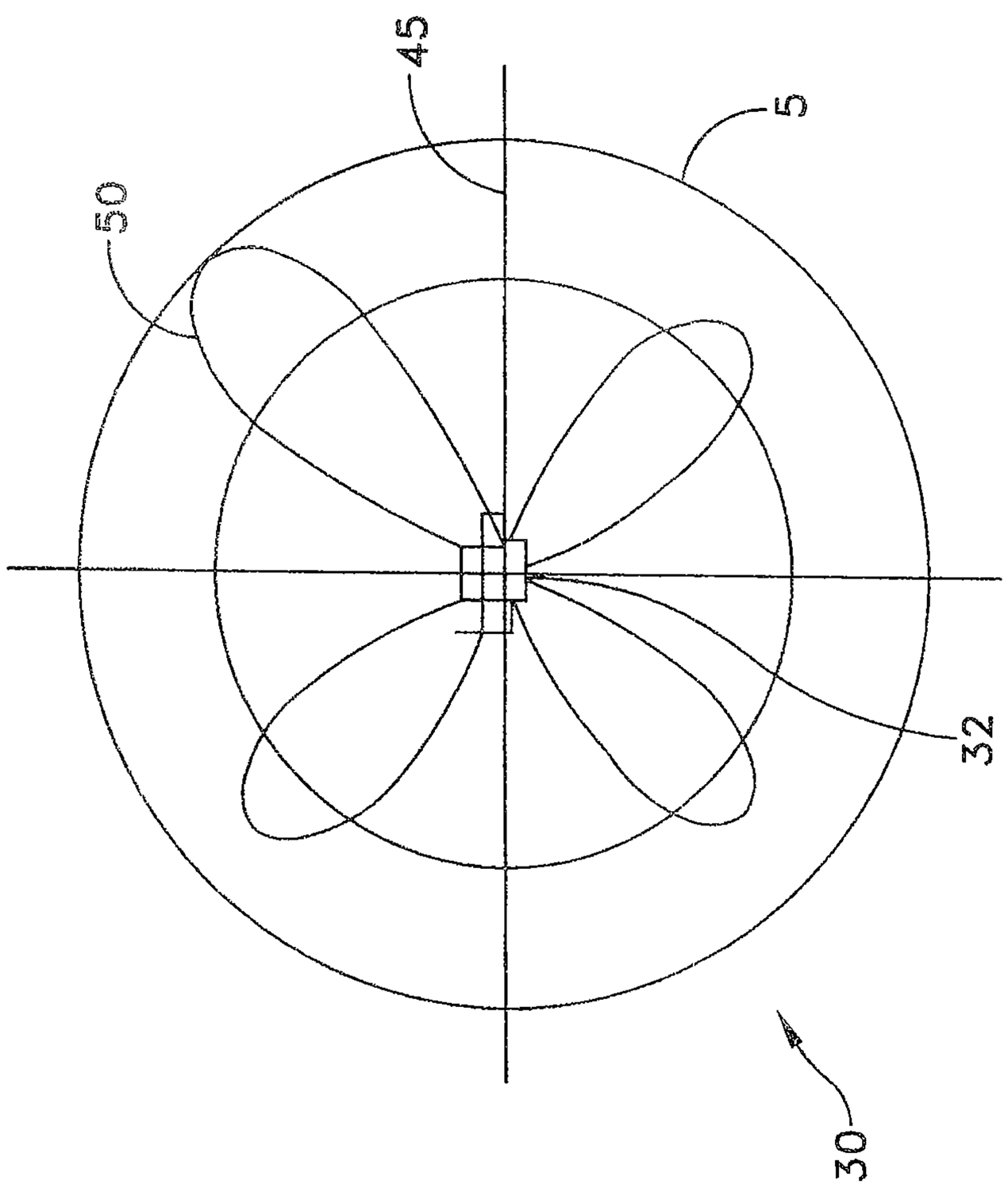


FIG. 8

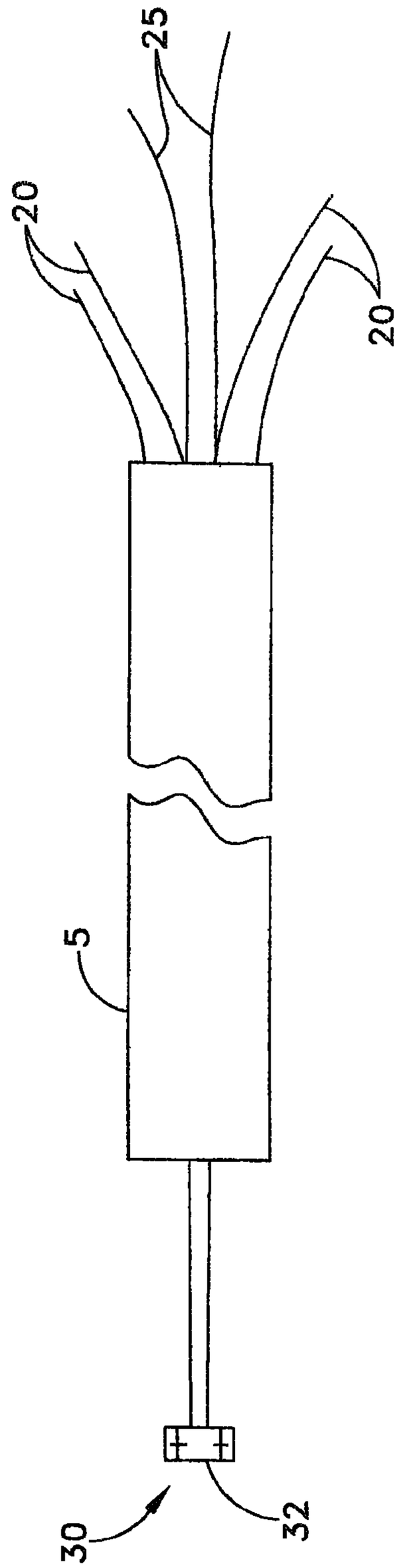


FIG. 9

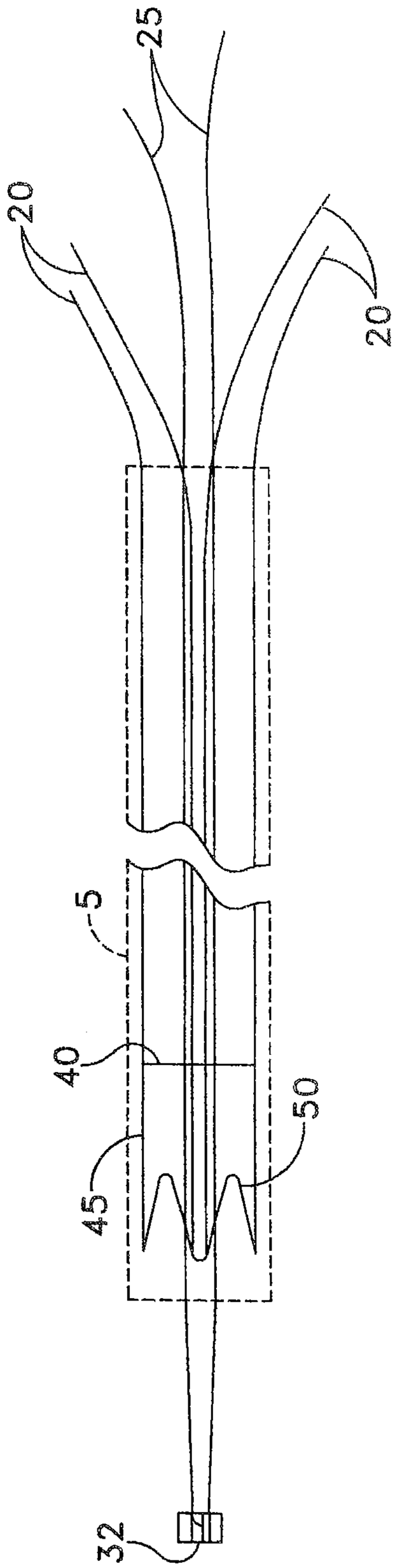
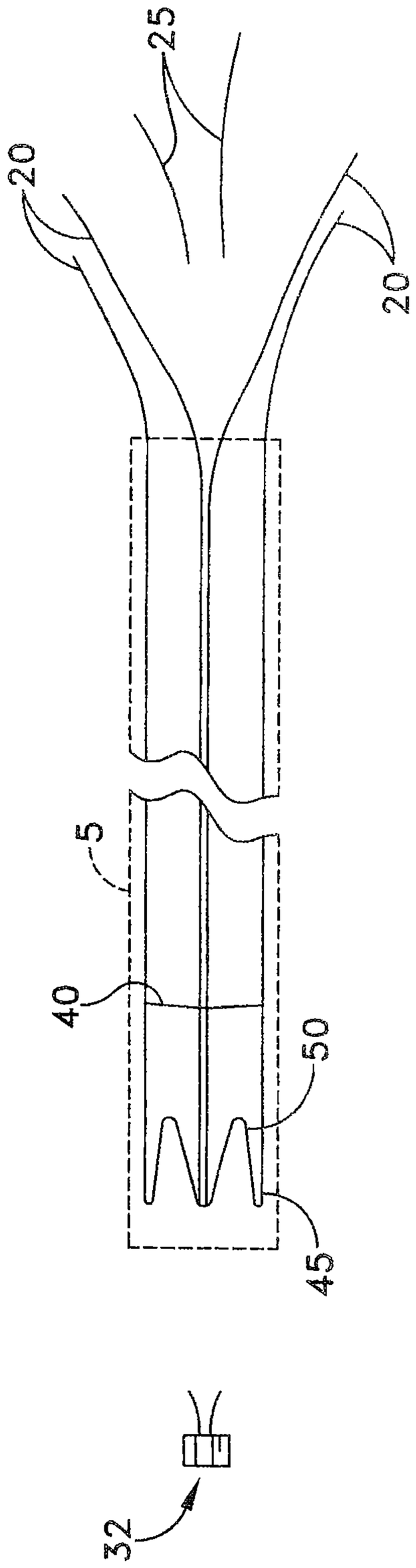


FIG. 10



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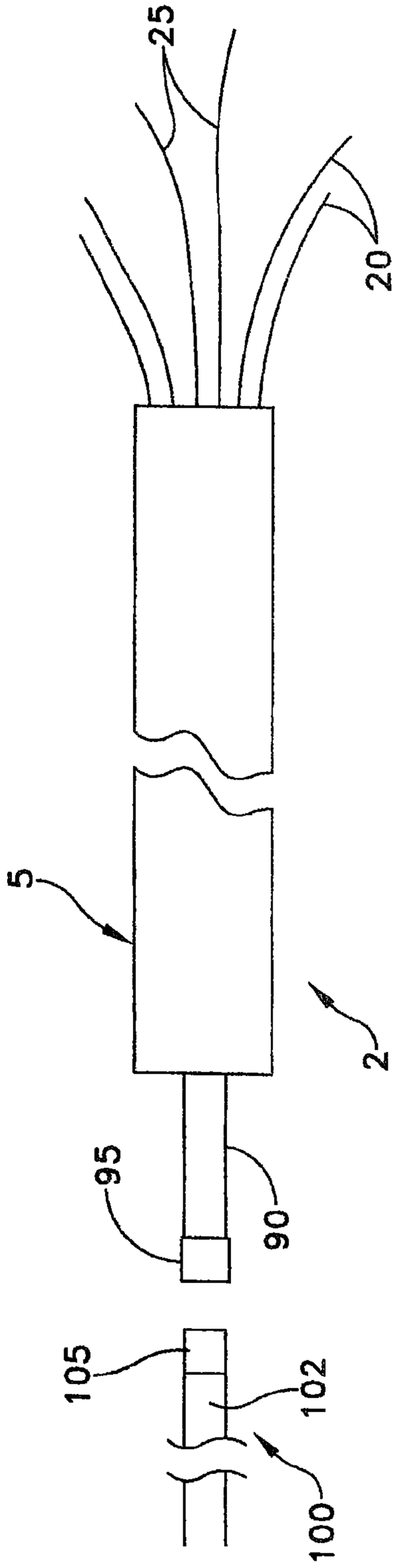

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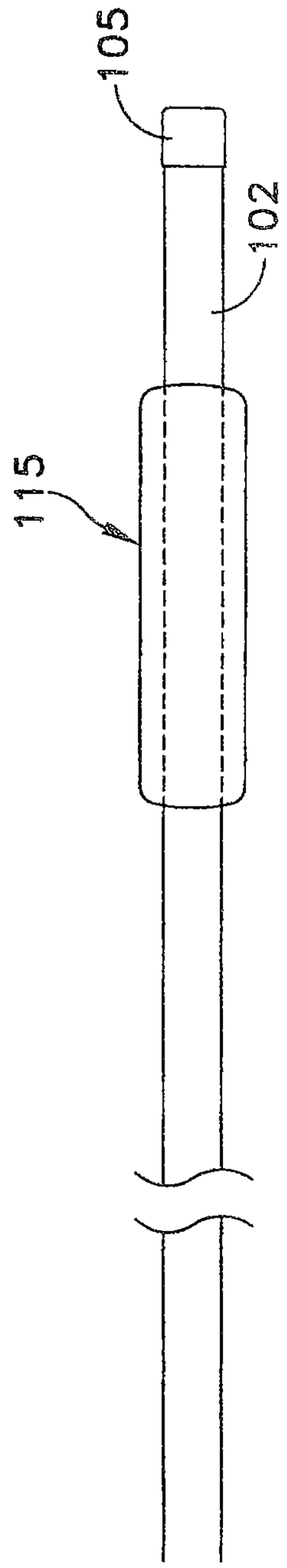
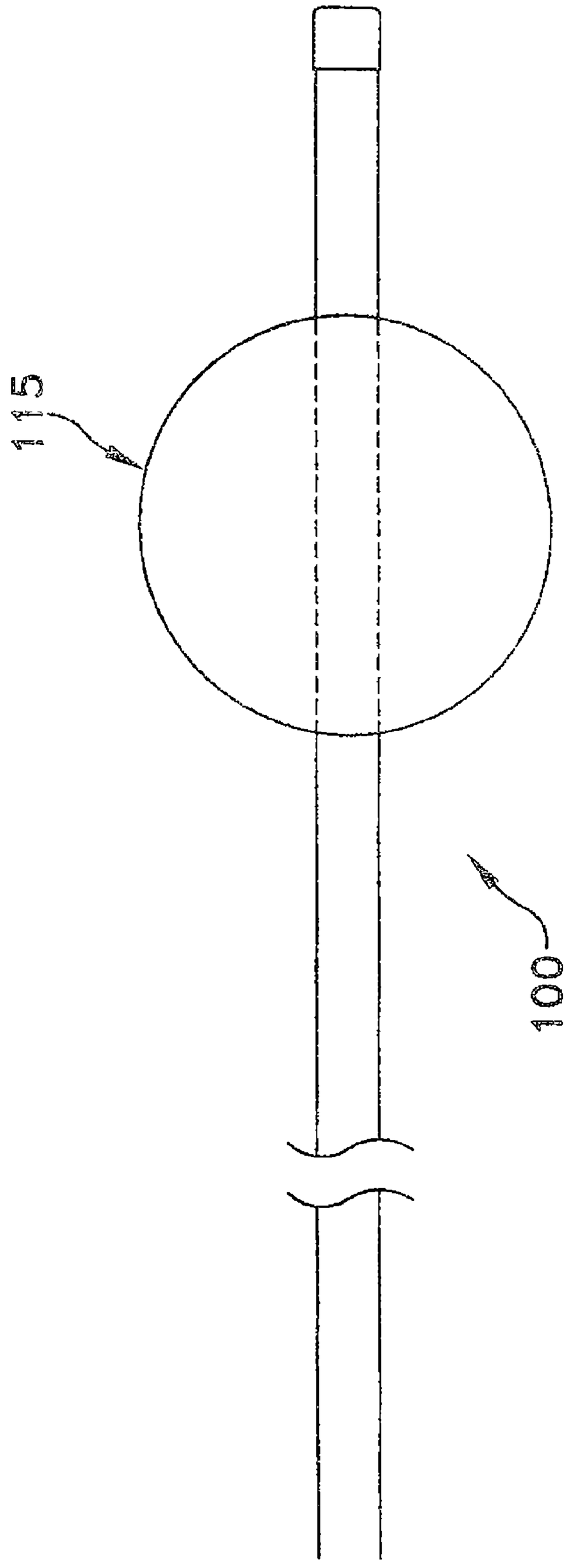


FIG. 13



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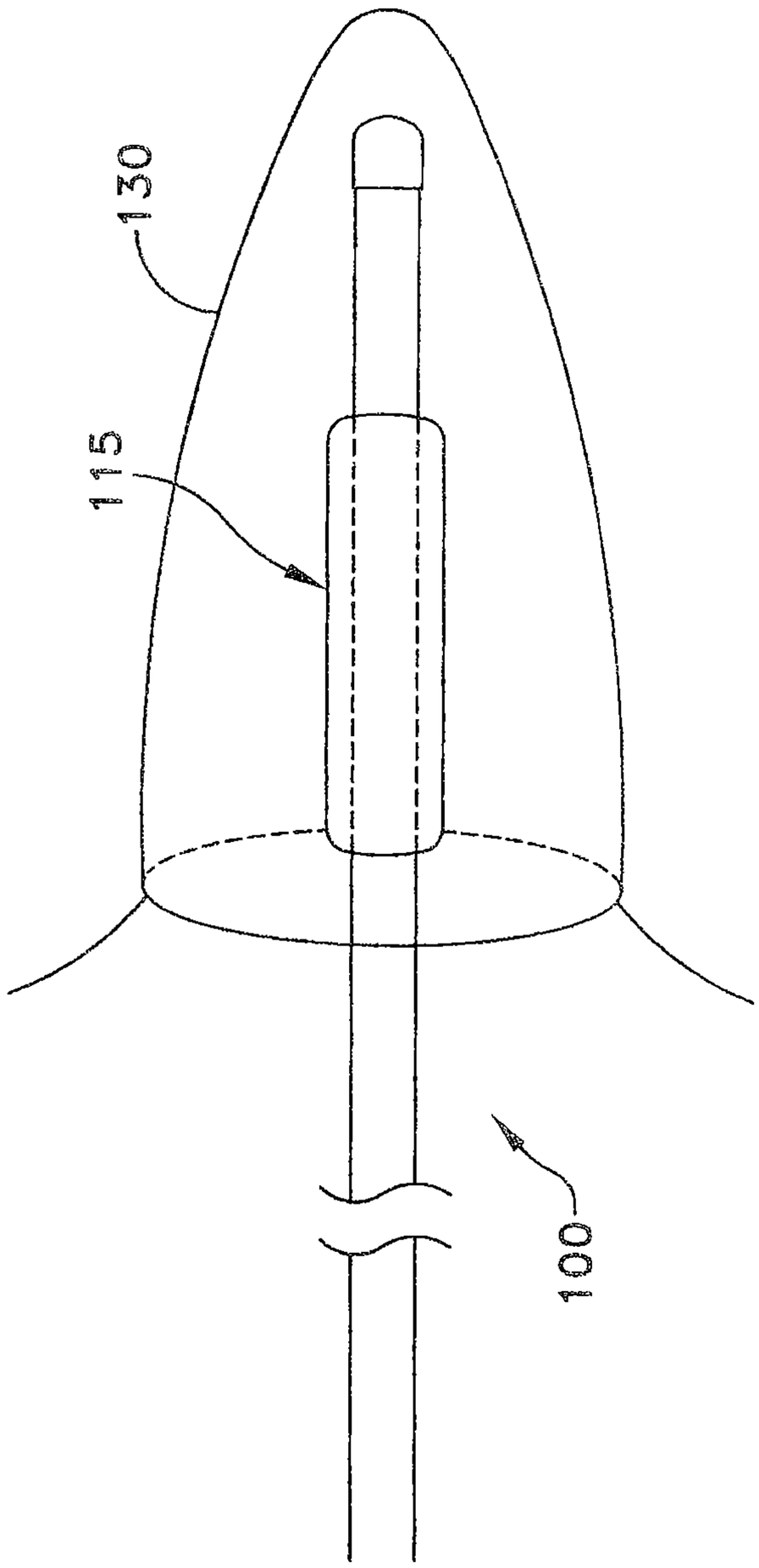


FIG. 15

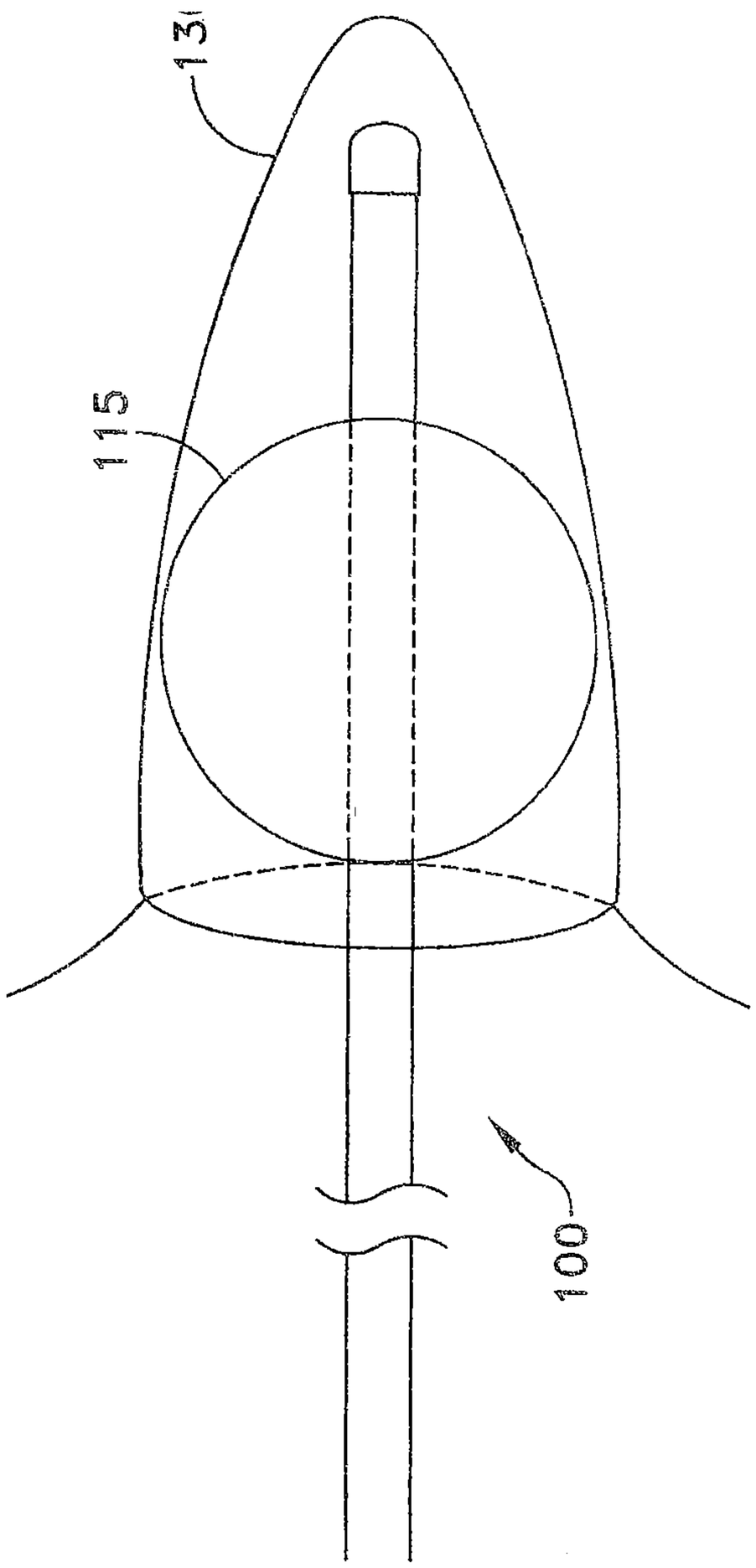


FIG. 16

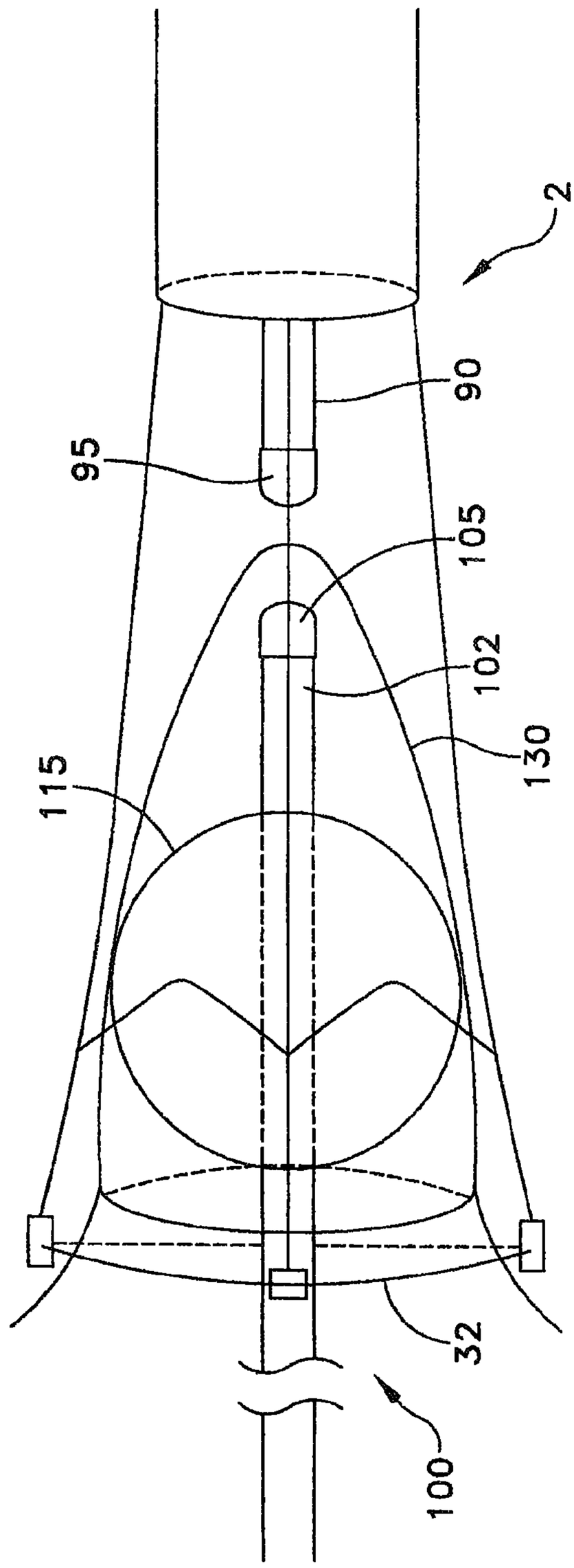
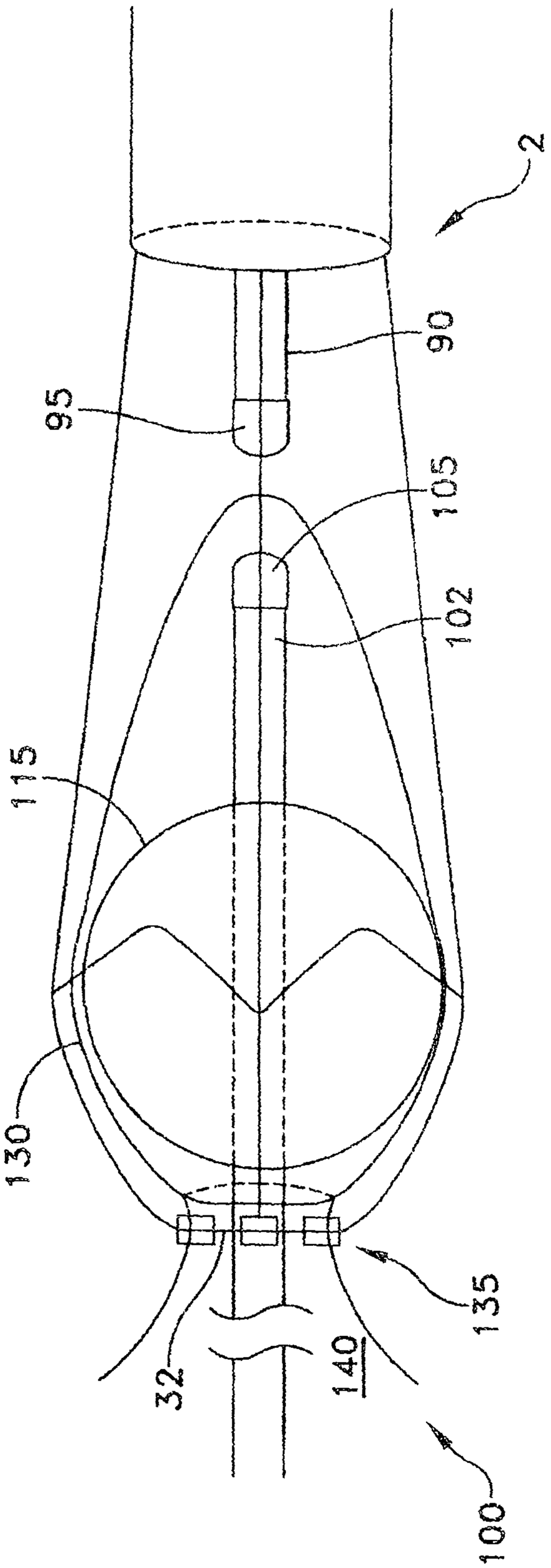


FIG. 17



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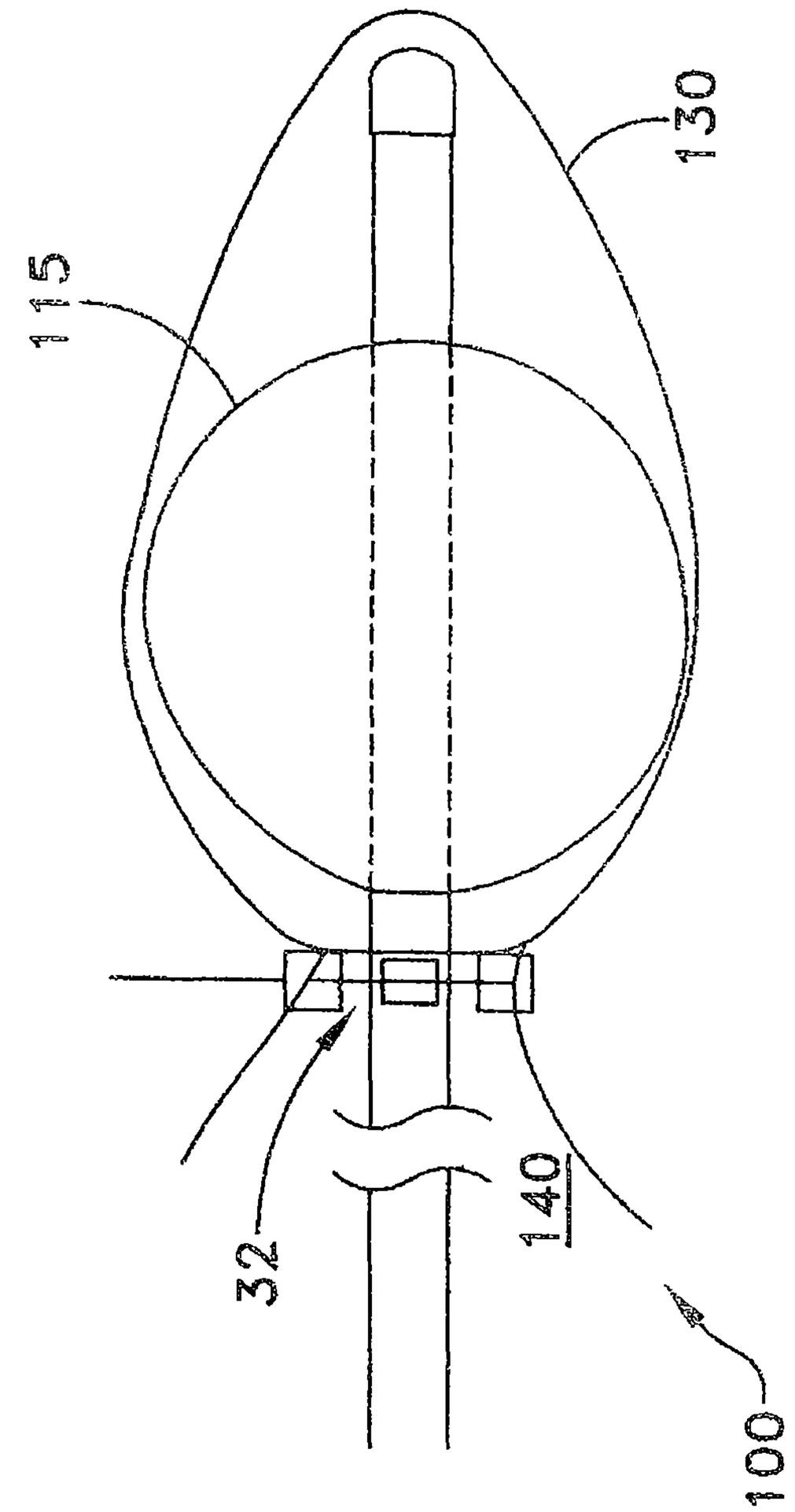

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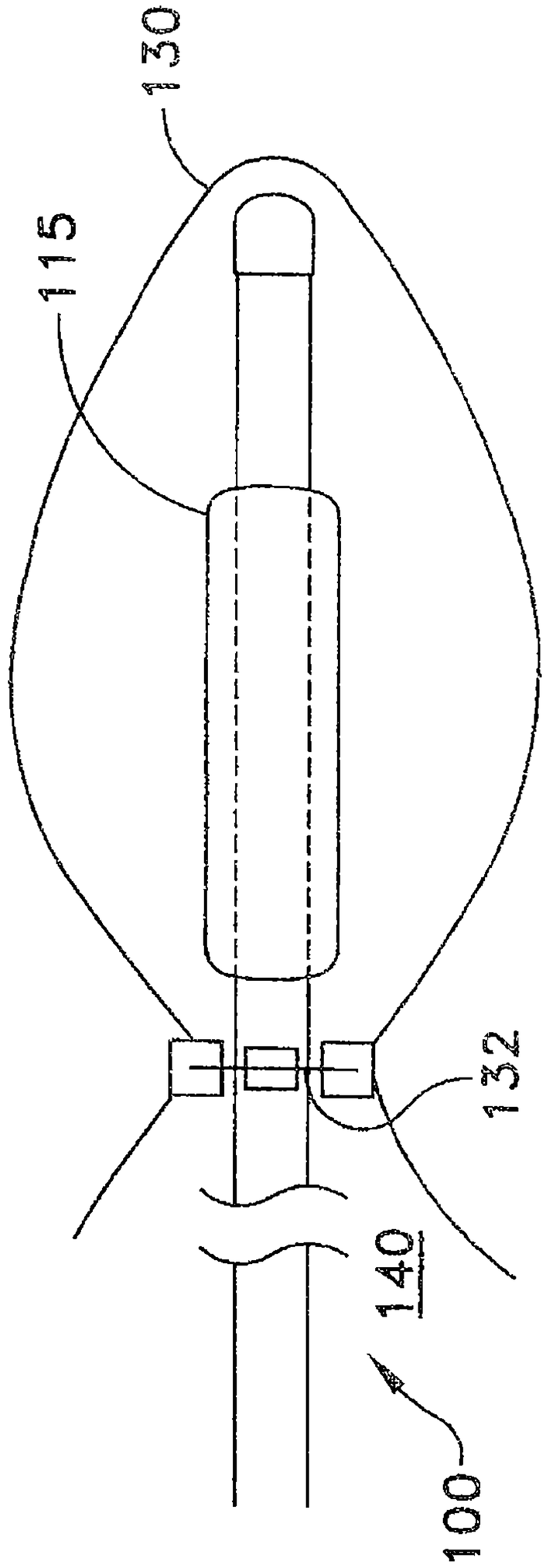


FIG. 20

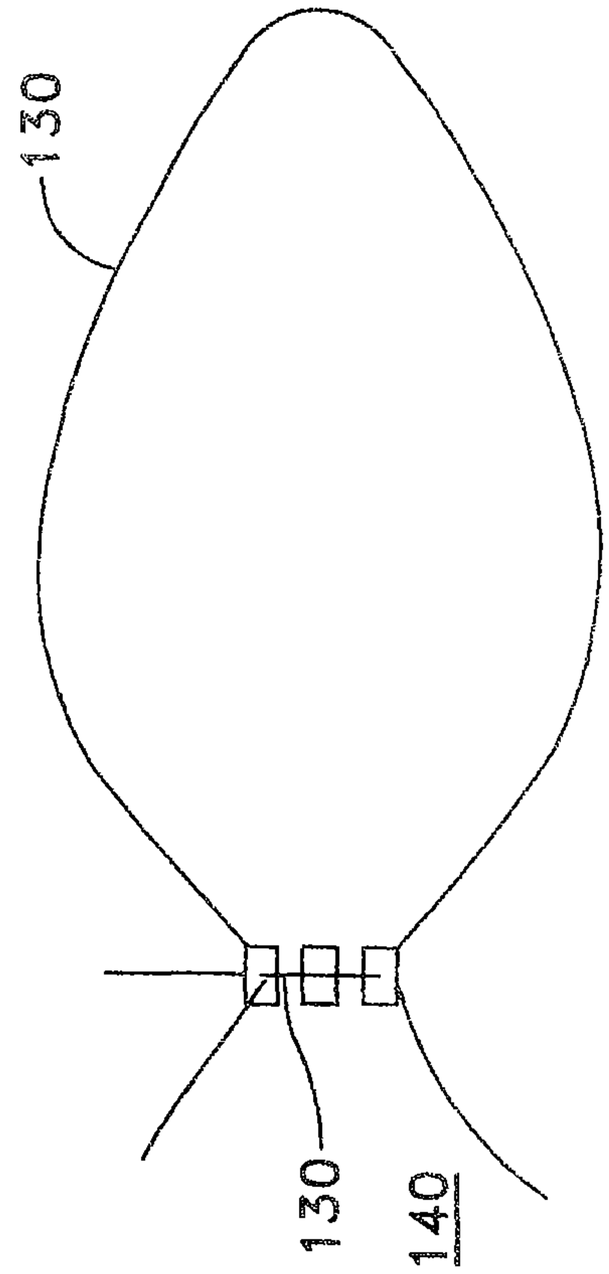
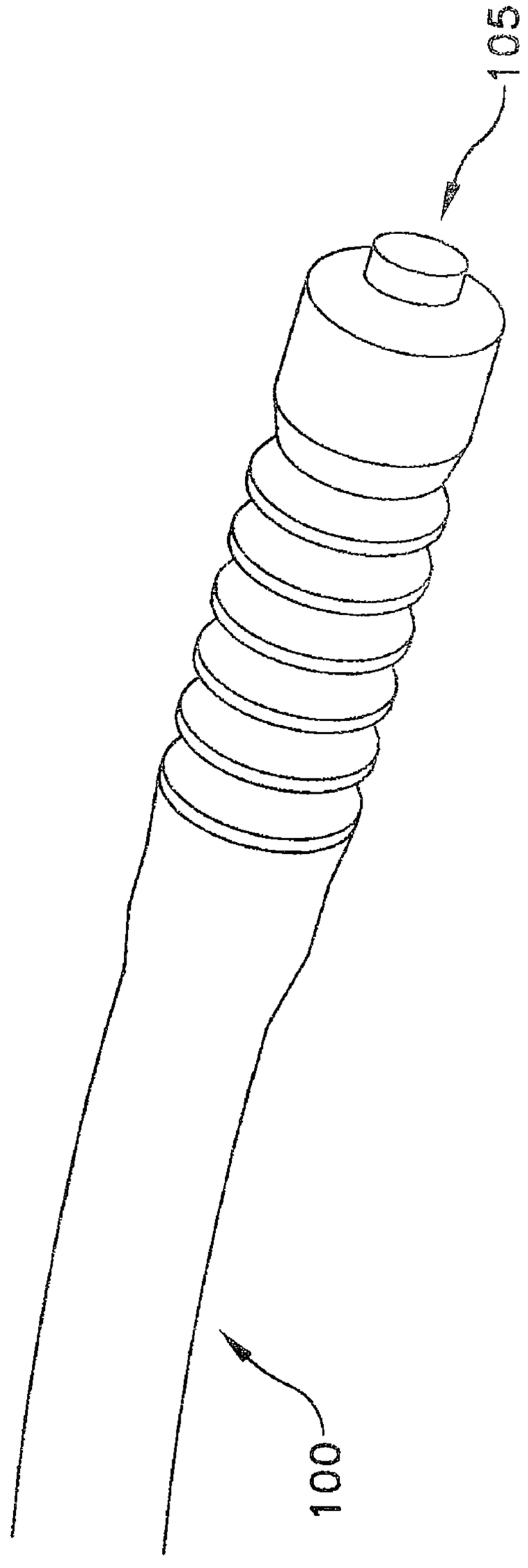


FIG. 21



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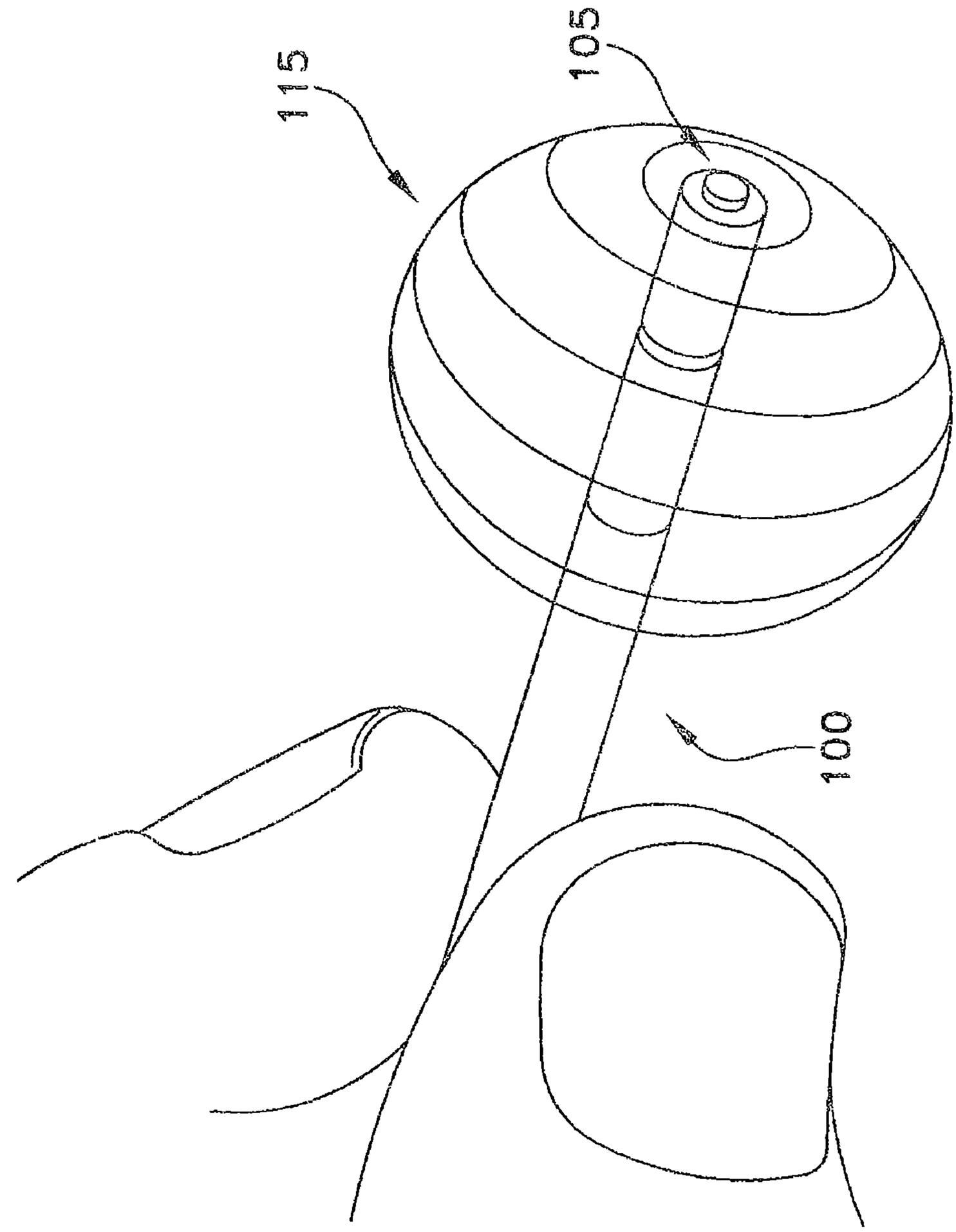

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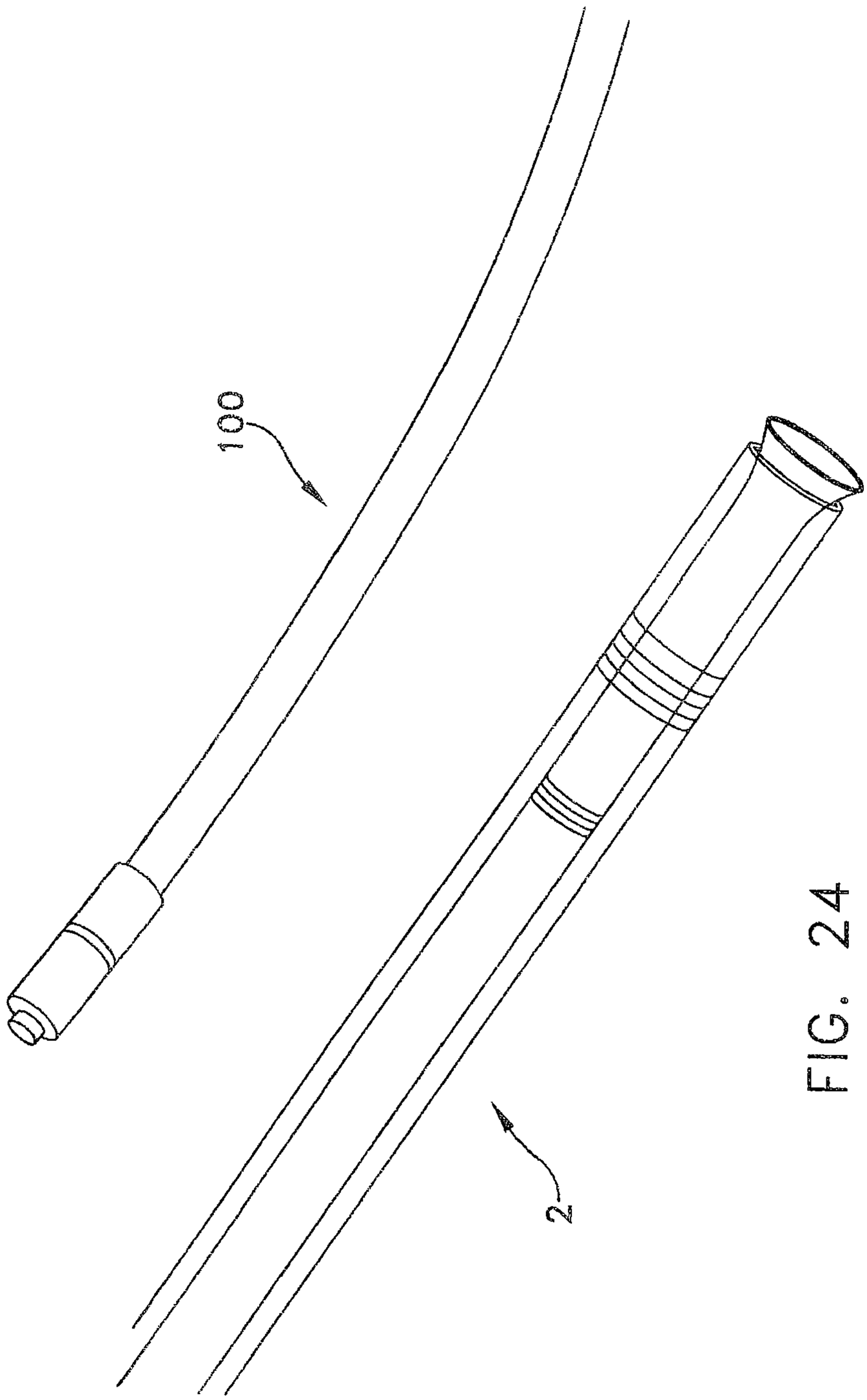

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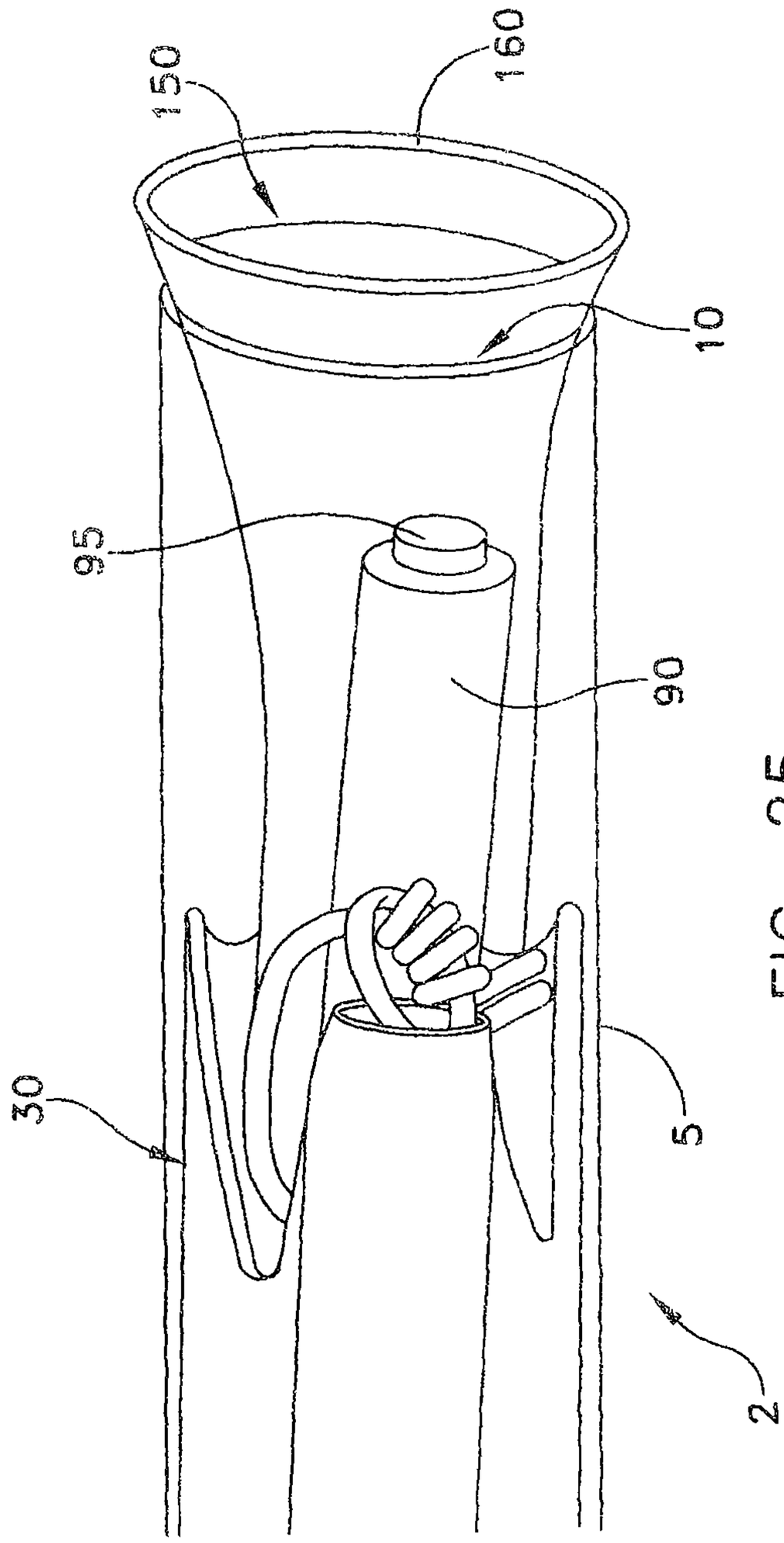

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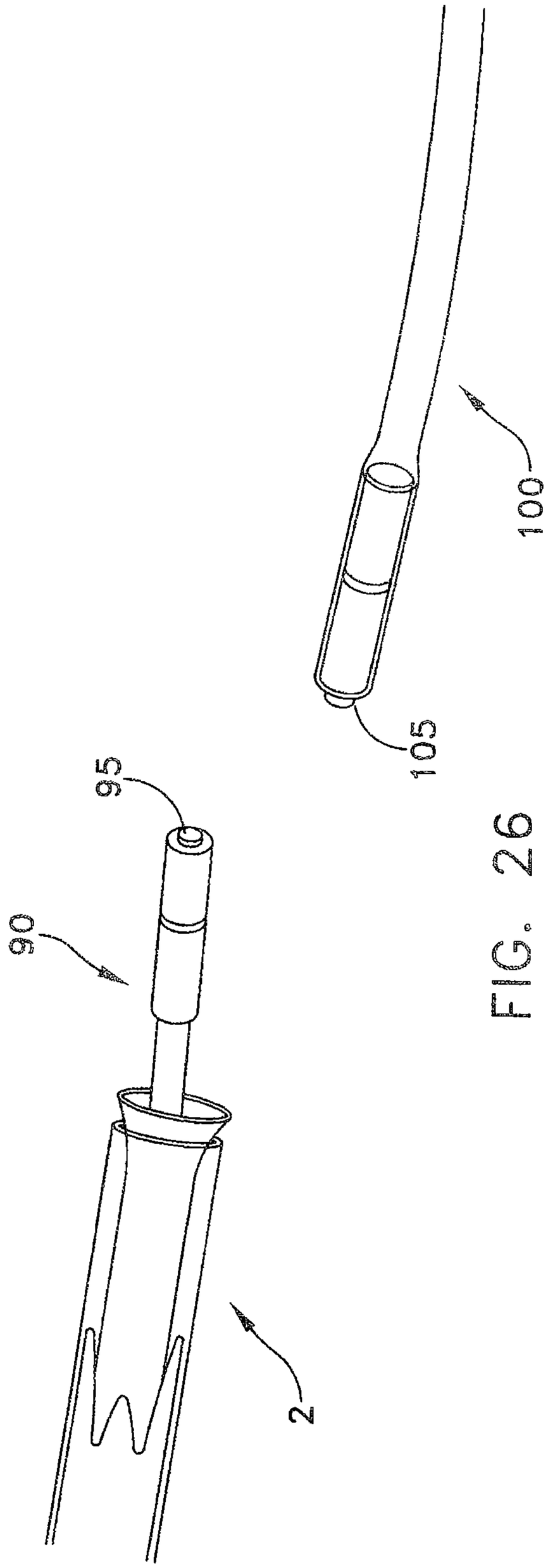

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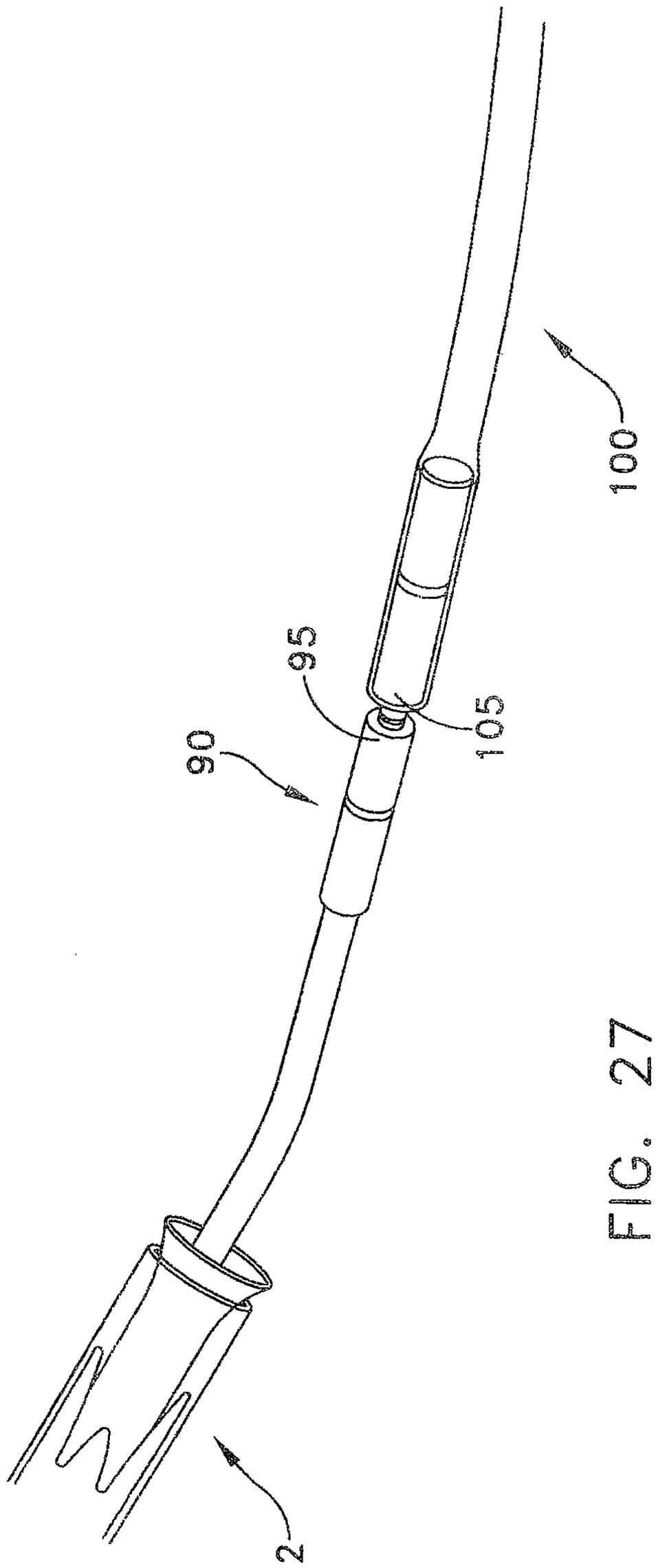

FIG. 27

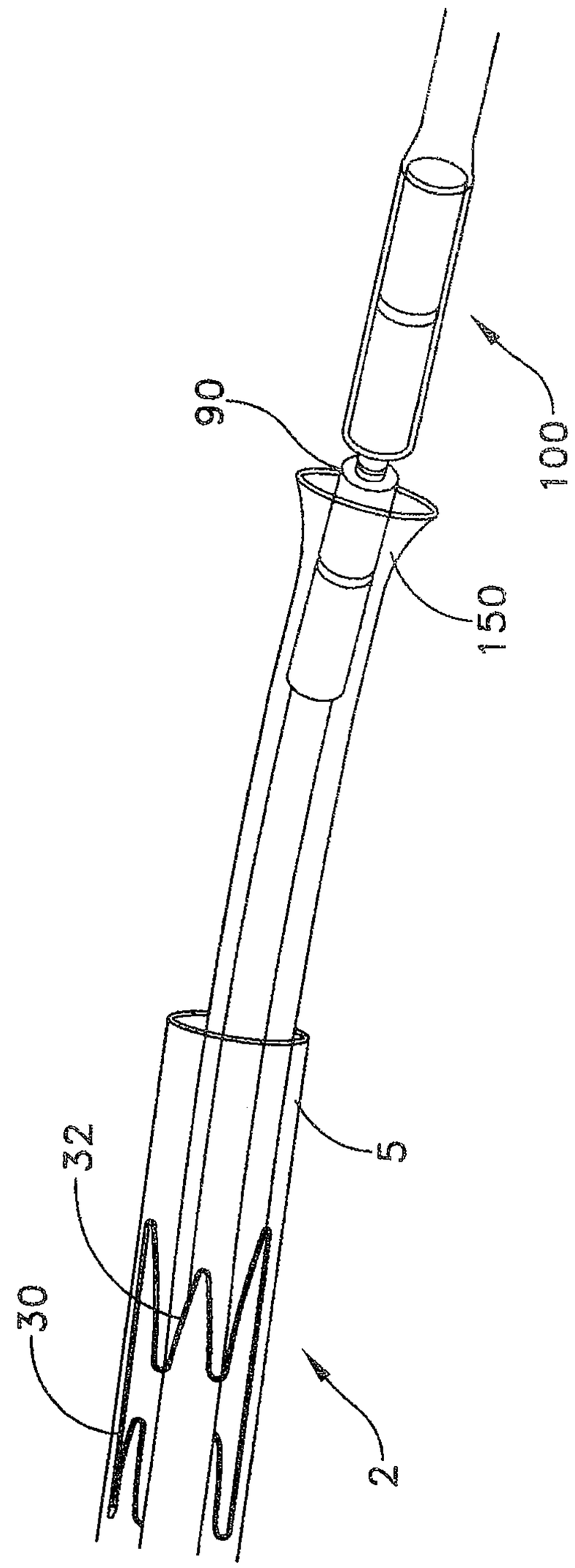

FIG. 28

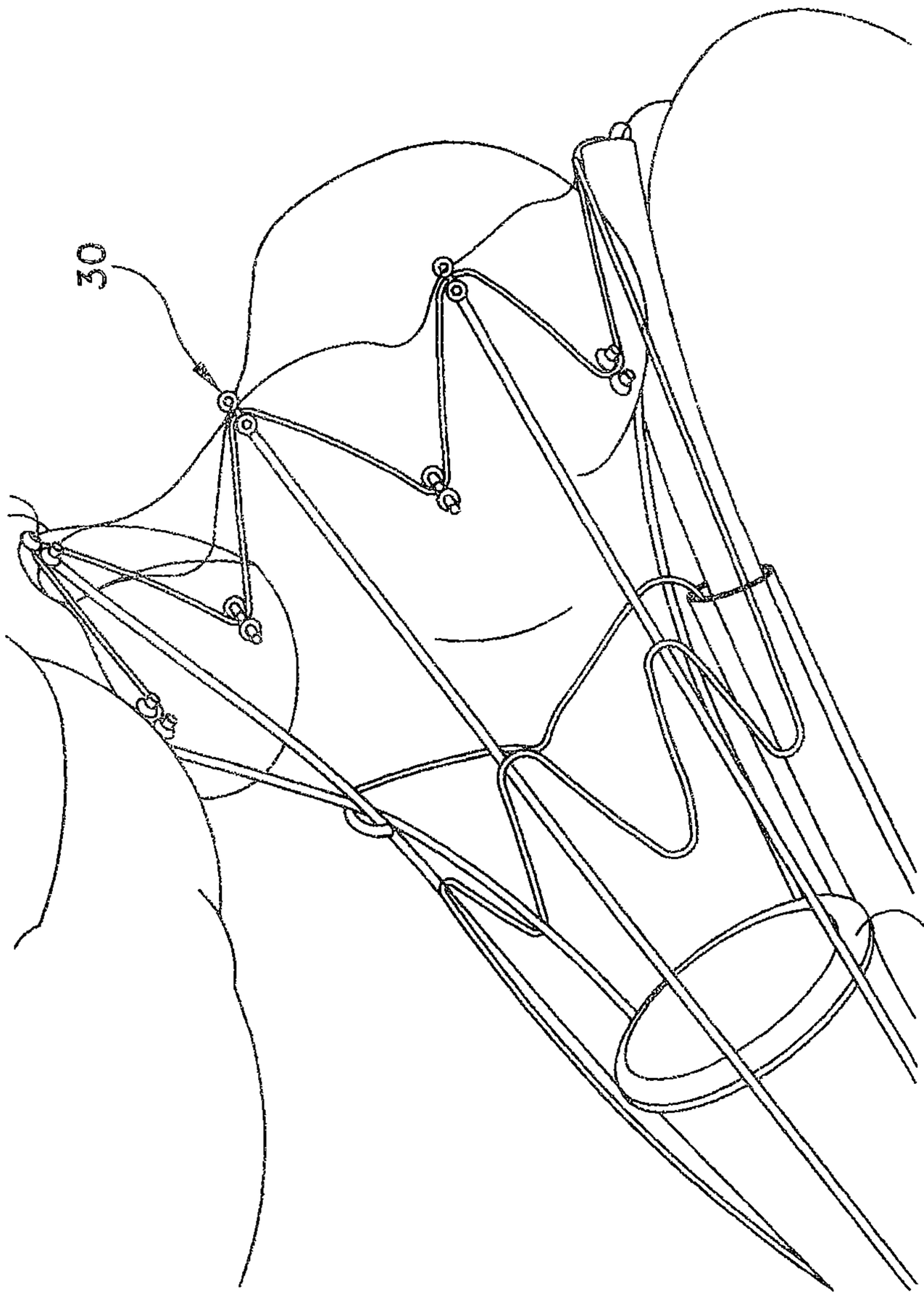

FIG. 29

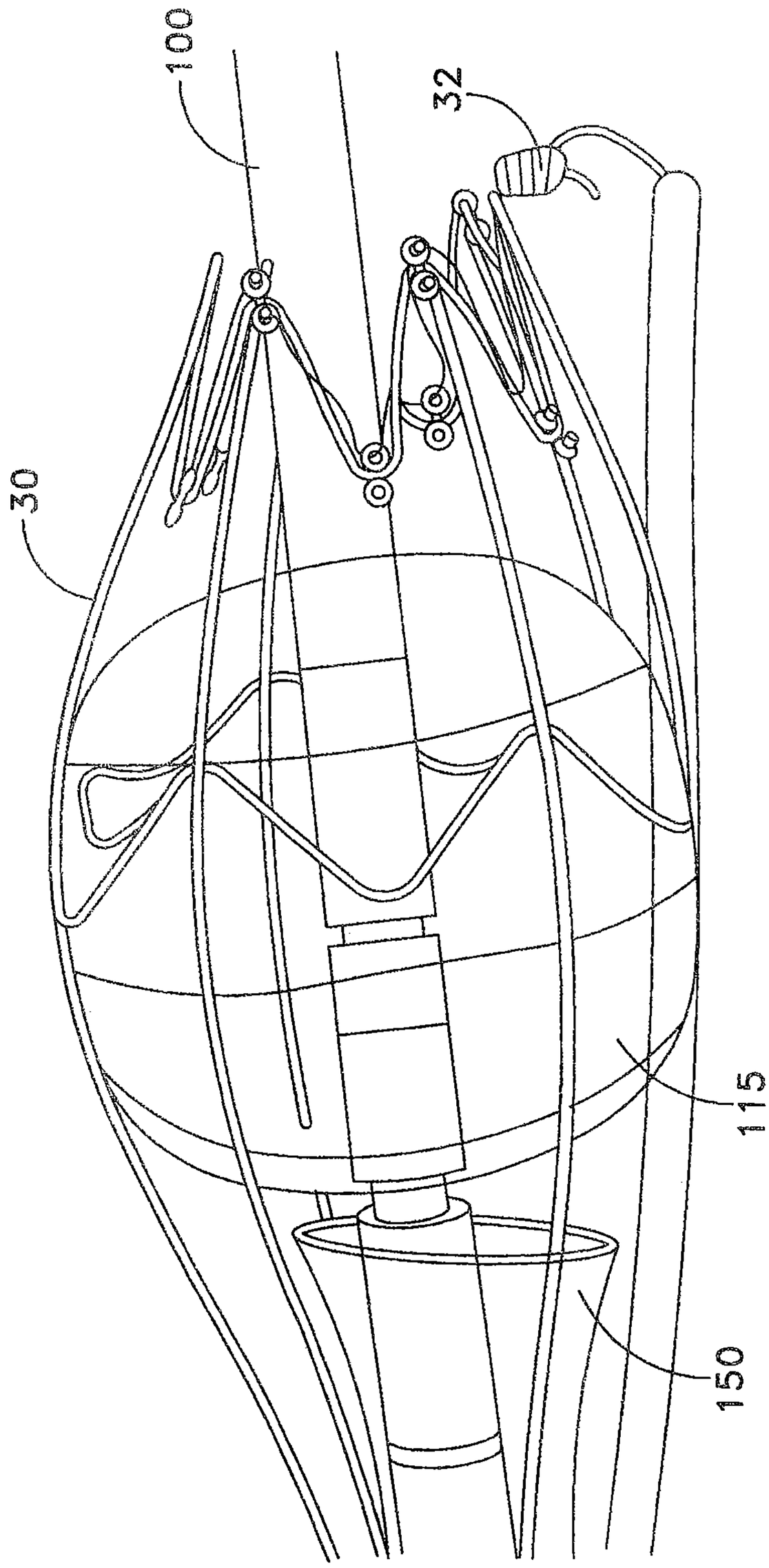

FIG. 30

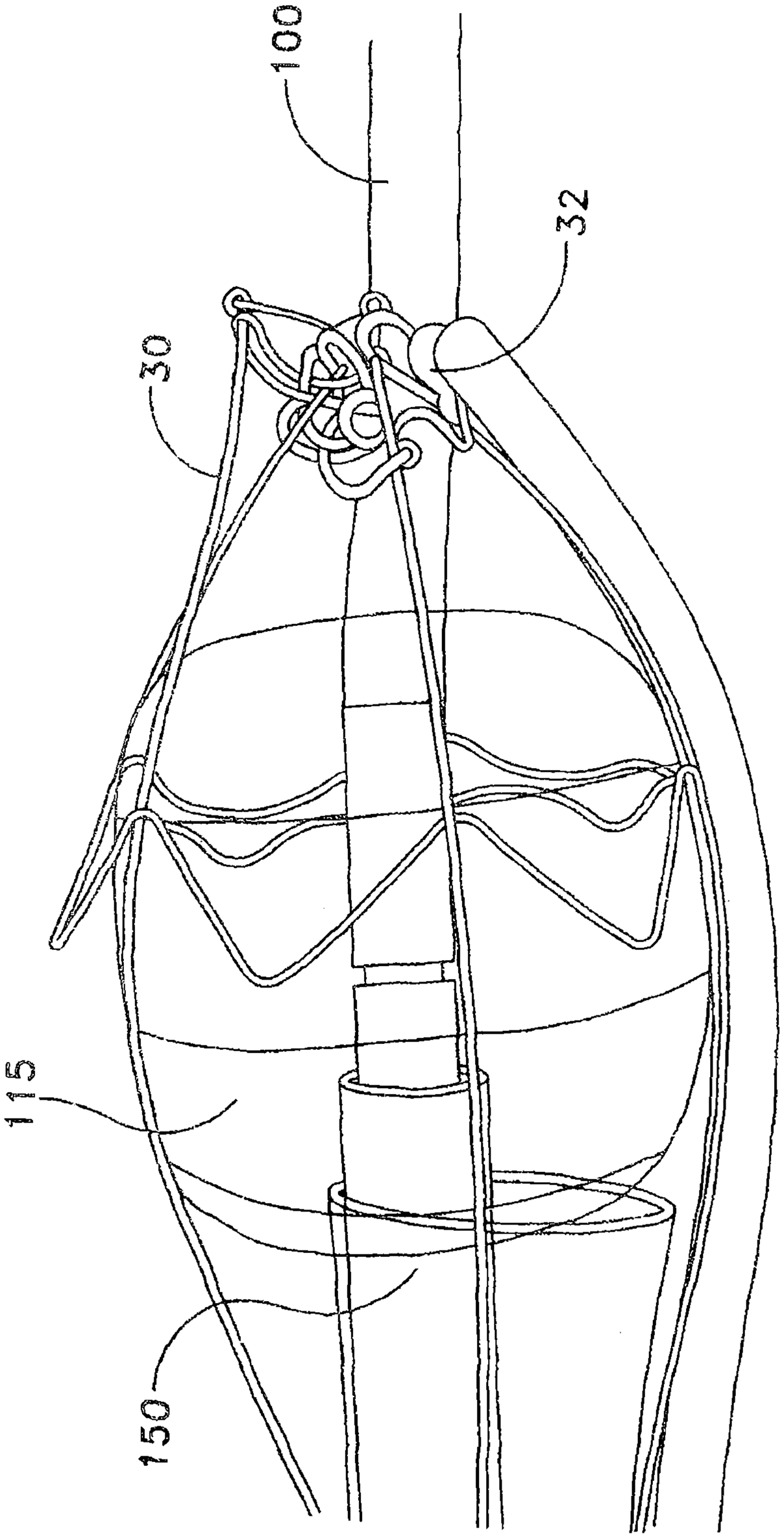

FIG. 31

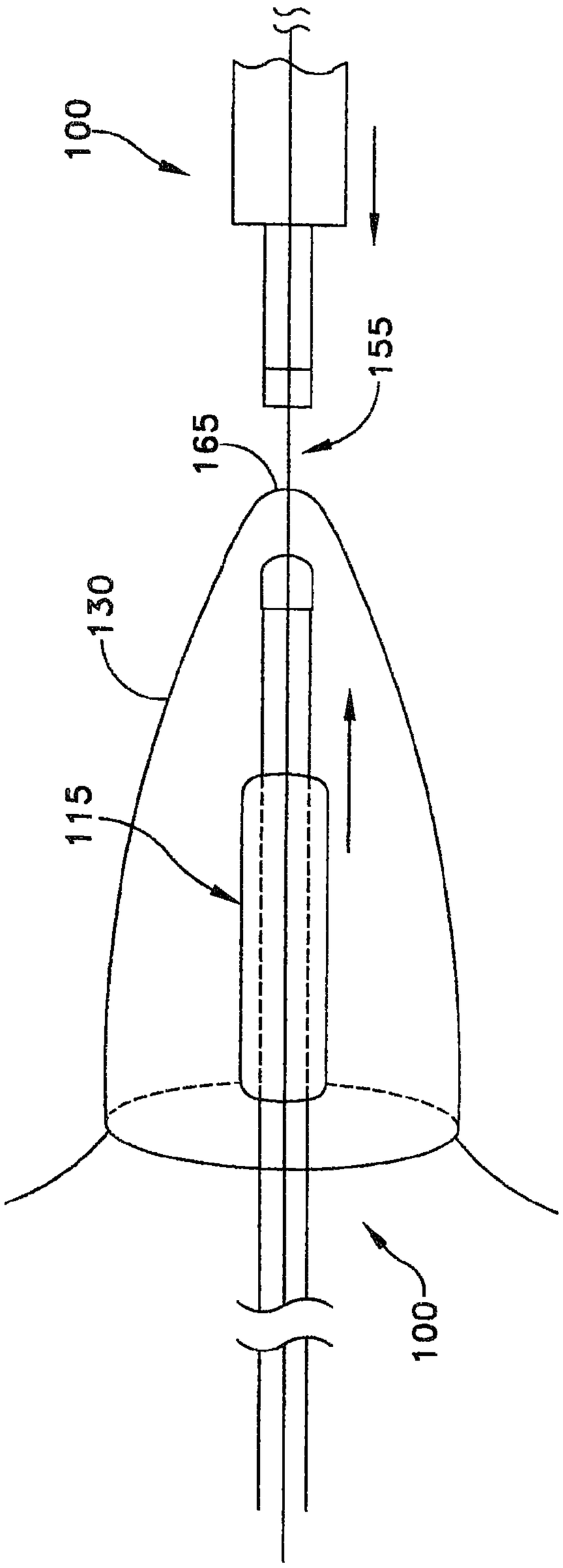

FIG. 32

APPARATUS AND METHOD FOR THE LIGATION OF TISSUE

CROSS-REFERENCE TO RELATED APPLICATIONS

This patent application is a continuation of, and claims priority to, U.S. patent application Ser. No. 10/963,371, filed on Oct. 11, 2004, which in turn claims priority to U.S. Provisional Patent Application Ser. Nos. 60/510,100 and 60/528,995, filed on Oct. 9, 2003 and Dec. 12, 2003 respectively. Each of these applications is incorporated herein by reference in their entirety.

FIELD OF THE INVENTION

This invention relates to apparatus and methods for ligating tissue, and more particularly to ligating cardiac tissue, and even more particularly to ligating tissue of the left atrium. In one preferred form of the present invention, ligation of the left atrial appendage is effected using a novel apparatus and method.

BACKGROUND OF THE INVENTION

Atrial fibrillation is a common problem that afflicts millions of patients. Unfortunately, atrial fibrillation often results in the formation of a thrombus, or clot, in the appendage of the left atrium. This presents a problem, inasmuch as the thrombus can dislodge and embolize to distant organs, resulting in adverse events such as a stroke. For this reason, most patients with atrial fibrillation are treated with a blood thinner so as to help prevent the formation of a thrombus in the left atrial appendage. Unfortunately, blood thinners pose a substantial health risk in their own right, particularly in the elderly.

An alternative treatment for atrial fibrillation is the ligation of the atrial appendage at its base. This procedure occludes the space in which the thrombus can form, thereby substantially eliminating the risk of forming a clot in the left atrial appendage and/or preventing a clot in the appendage from embolizing. Surgeons have been ligating atrial appendages for years during open surgical procedures. Though effective, this approach requires general anesthesia and surgically opening the chest, which presents additional serious health risks to the patient. Therefore, such open-chest ligation of the atrial appendage is normally restricted to situations where the chest is already being surgically opened for other reasons, or where the patient is at a particularly high risk of embolizing.

Recently, catheter-based techniques have been developed for occluding the left atrial appendage space by placing mechanical devices inside the left atrial appendage. This is done under fluoroscopic and/or echocardiographic guidance without the need for a major chest incision or general anesthesia. Unfortunately, however, these techniques require the implantation of mechanical intracardiac devices which, over time, may result in clot formation, incomplete occluding of the appendage space, infection, etc.

SUMMARY OF THE INVENTION

These and other issues are addressed by the present invention, which comprises a novel catheter-based system which ligates the left atrial appendage (LAA) on the outside of the heart, preferably using a combination of catheters and/or instruments, e.g., a guide catheter positioned inside the left atrial appendage which may assist in locating the left atrial appendage and/or assist in the optimal placement of a ligature

on the outside of the appendage, and a ligating catheter and/or instrument outside the heart in the pericardial space to set a ligating element at the neck of the left atrial appendage. As a result, this novel approach provides the advantages of both the open surgical approach (i.e., successful ligation of the atrial appendage on the outside of the heart, while avoiding implantation of a mechanical intracardiac device within the heart), and the catheter-based approach (i.e., providing rapid and reliable access to the left atrial appendage without the need for a major chest incision or general anesthesia).

The apparatus and method described herein are primarily intended to ligate the left atrial appendage, however, the apparatus and method may also be used in the same or similar constructions to stabilize, suture, and/or ligate any other tissue in the body. By way of example but not limitation, using the apparatus and method described herein, other tissues of the heart (such as the left ventricle) may be manipulated so as to alter the conformational geometry of the heart into a more favorable shape.

In another form of the invention, there is provided a guide catheter for use in conjunction with a ligating catheter for ligating tissue, comprising:

a shaft having a distal end; and

an alignment element disposed on the distal end of the shaft, wherein the alignment element interacts with a counterpart alignment element on the ligating catheter so as to facilitate alignment of the ligating catheter with the guide catheter.

In another form of the invention, there is provided a guide catheter for use in conjunction with a ligating catheter for ligating tissue, comprising:

a shaft having a distal end; and

an expandable element connected to the distal end of the shaft, wherein the expandable element is configured to expand to a size corresponding to the interior of the left atrial appendage.

In another form of the invention, there is provided a ligating catheter for ligating tissue, comprising:

a hollow shaft having a distal end;

a ligating subassembly comprising a plurality of expandable arms arranged in an arcuate configuration and releasably supporting a ligating element thereon, the ligating subassembly being slidably received within the hollow shaft and adapted to move between (i) a retracted position wherein the expandable arms are received within the hollow shaft, and (ii) an extended position wherein the expandable arms project from the distal end of the hollow shaft, with the expandable arms holding the ligating element radially outboard of the shaft when the ligating subassembly is in its second position.

In another form of the invention, there is provided a ligating catheter for ligating tissue, comprising:

a hollow shaft having a distal end;

a ligating subassembly comprising a plurality of expandable arms arranged in an arcuate configuration and releasably supporting a ligating element thereon, the ligating subassembly being slidably received within the hollow shaft and adapted to move between (i) a retracted position wherein the expandable arms are received within the hollow shaft, and (ii) an extended position wherein the expandable arms project from the distal end of the hollow shaft, with the expandable arms holding the ligating element radially outboard of the shaft when the ligating subassembly is in its second position;

an alignment element mounted to the shaft, wherein the alignment element interacts with a counterpart alignment element on a guide catheter disposed within the tissue to be ligated; and

gripping apparatus for gripping tissue, wherein the gripping apparatus comprises a suction tube mounted to the hollow shaft.

In another form of the invention, there is provided a system for ligating tissue comprising:

a guide catheter comprising:

a shaft having a distal end; and

an alignment element disposed on the distal end of the shaft, wherein the alignment element interacts with a counterpart alignment element on a ligating catheter so as to facilitate alignment of the ligating catheter with the guide catheter; and

a ligating catheter for ligating tissue, comprising:

a hollow shaft having a distal end;

a ligating subassembly comprising a plurality of expandable arms arranged in an arcuate configuration and releasably supporting a ligating element thereon, the ligating subassembly being slidably received within the hollow shaft and adapted to move between (i) a retracted position wherein the expandable arms are received within the hollow shaft, and (ii) an extended position wherein the expandable arms project from the distal end of the hollow shaft, with the expandable arms holding the ligating element radially outboard of the shaft when the ligating subassembly is in its second position; and

an alignment element mounted to the shaft, wherein the alignment element interacts with counterpart alignment element on the guide catheter when the guide catheter is disposed within the tissue to be ligated.

In another form of the invention, there is provided a system for ligating tissue comprising:

a guide catheter comprising:

a shaft having a distal end; and

an alignment element disposed on the distal end of the shaft, wherein the alignment element interacts with a counterpart alignment element on a ligating catheter so as to facilitate alignment of the ligating catheter with the guide catheter; and

an expandable element connected to the distal end of the shaft, wherein the expandable element is configured to expand to a size corresponding to the interior of the left atrial appendage; and

a ligating catheter for ligating tissue, comprising:

a hollow shaft having a distal end;

a ligating subassembly comprising a plurality of expandable arms arranged in arcuate configuration and releasably supporting a ligating element thereon, the ligating subassembly being slidably received within the hollow shaft and adapted to move between (i) a retracted position wherein the expandable arms are received within the hollow shaft, and (ii) an extended position wherein the expandable arms project from the distal end of the hollow shaft, with the expandable arms holding the ligating element radially outboard of the shaft when the ligating subassembly is in its second position;

an alignment element mounted to the shaft, wherein the alignment element interacts with counterpart alignment element on the guide catheter when the guide catheter is disposed within the tissue to be ligated; and

a gripping apparatus for gripping tissue, wherein the gripping apparatus comprises a suction tube mounted to the hollow shaft.

In another form of the invention, there is provided a method for ligating tissue, comprising:

positioning a guide catheter within the interior of the tissue to be ligated, wherein the guide catheter comprises an alignment element for interacting with a counterpart alignment element on a ligating catheter;

advancing a ligating catheter so as to position a ligating element about the tissue to be ligated, wherein the ligating catheter interacts with the alignment element on the guide catheter when positioning the ligating element about the tissue to be sutured; and

contracting the ligating element about the tissue, whereby to ligate the tissue.

In another form of the invention, there is provided a method for ligating tissue, comprising:

providing a guide catheter and a ligating catheter, wherein the guide catheter comprises an alignment element for interacting with a counterpart aligning element on the ligating catheter so as to facilitate alignment of the ligating catheter with the guide catheter;

positioning the guide catheter within the tissue to be ligated;

using the alignment elements to align the ligating catheter with the guide catheter and about the tissue to be ligated; and

ligating the tissue with the ligating catheter.

In another form of the invention, there is provided a system for ligating tissue comprising:

a wire extending from the interior of the left atrial appendage, through the side wall of the left atrial appendage, and out the pericardium;

a guide catheter slidably mounted on the wire, comprising:

a shaft having a distal end; and

an expandable element connected to the distal end of the shaft, wherein the expandable element is configured to expand to a size corresponding to the interior of the left atrial appendage; and

a ligating catheter for ligating tissue, comprising:

a hollow shaft having a distal end; and

a ligating subassembly comprising a plurality of expandable arms arranged in an arcuate configuration and releasably supporting a ligating element thereon, the ligating subassembly being slidably received within the hollow shaft and adapted to move between (i) a retracted position wherein the expandable arms are received within the hollow shaft, and (ii) an extended position wherein the expandable arms project from the distal end of the hollow shaft, with the expandable arms holding the ligating element radially outboard of the shaft when the ligating subassembly is in its second position.

In another form of the invention, there is provided a method for performing a procedure on a body structure, comprising:

inserting a first device with an alignment element into the body structure;

positioning a second device outside of the body structure;

aligning the first device with the second device with the alignment element; and

performing a procedure on the body structure with the devices.

BRIEF DESCRIPTION OF THE DRAWINGS

These and other objects and features of the present invention will be more fully disclosed or rendered obvious by the following detailed description of the preferred embodiments of the invention, which are to be considered together with the accompanying drawings wherein like numbers refer to like parts, and further wherein:

FIG. **1** is a side view of a ligating catheter, with the catheter's ligation subassembly being disposed in a retracted position;

FIG. **2** is a view like that of FIG. **1**, except that portions of the ligating catheter have been shown in phantom;

FIG. **3** is an end view of the ligating catheter shown in FIG. **1**;

FIG. **4** is a view like that of FIG. **1**, except that the catheter's ligation subassembly is shown in an extended position;

FIG. **5** is a view like that of FIG. **4**, except that portions of the ligating catheter have been shown in phantom;

FIG. **6** is an end view of the ligating catheter shown in FIG. **4**;

FIG. **7** is a view like that of FIG. **4**, but with the ligating element being contracted;

FIG. **8** is an end view of the ligating catheter shown in FIG. **7**;

FIG. **9** is a view like that of FIG. **7**, but with the catheter's ligation subassembly fully retracted;

FIG. **10** is a view like that of FIG. **9**, except that certain portions of the ligating catheter are shown in phantom;

FIG. **11** is a view like that of FIG. **10**, except that the ligating element has been severed from the ligating catheter;

FIG. **12** is a side view showing the ligating catheter in combination with a guide catheter;

FIG. **13** is a side view of the distal tip of the guide catheter, with the catheter's expanding element being shown in a contracted position;

FIG. **14** is a view like that of FIG. **13**, except that the catheter's expanding element is shown in an expanded position;

FIG. **15** is a view showing the distal tip of the guide catheter placed within the left atrial appendage, with the catheter's expanding element being shown in a contracted position;

FIG. **16** is a view like that of FIG. **15**, except that the catheter's expanding element is shown in an expanded position;

FIG. **17** shows the guide catheter placed within the left atrial appendage, the guide catheter's expanding element placed in its expanded state, and the ligating catheter placed over the left atrial appendage;

FIG. **18** is a view like that of FIG. **17**, except that the ligating catheter has had its ligating element contracted about the neck of the left atrial appendage;

FIG. **19** is a view like that of FIG. **18**, except that the ligating catheter has been withdrawn from the surgical site;

FIG. **20** is a view like that of FIG. **19**, except that the guide catheter's expanding element has been contracted;

FIG. **21** is a view like that of FIG. **20**, except that the guide catheter has been withdrawn from the left atrial appendage;

FIG. **22** is a schematic view showing the distal end of the guide catheter;

FIG. **23** is a schematic view showing the guide catheter's balloon in an expanded condition;

FIG. **24** is a schematic view showing the ligating catheter and the guide catheter;

FIG. **25** is a schematic view showing the distal end of the ligating catheter;

FIGS. **26** and **27** are schematic views showing the distal ends of the ligating catheter and the guide catheter orienting an end-to-end fashion through the use of magnets;

FIG. **28** is a schematic view showing a flared suction tube extending out of the ligating catheter's outer tube;

FIG. **29** is a schematic view showing details of the ligating subassembly;

FIG. **30** is a schematic view showing the ligating subassembly extending over the guide catheter's inflated balloon;

FIG. **31** is a schematic view showing the ligature being drawn taut on the outboard side of the guide catheter's balloon; and

FIG. **32** is a schematic view showing a single wire track passing from the interior of the left atrial appendage out through the pericardium, whereby a guide catheter and/or a ligating catheter may be advanced to the surgical site.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Ligating Catheter

Looking first at FIG. **1**, there is shown a ligating catheter **2** formed in accordance with the present invention. Ligating catheter **2** comprises an elongated tube or cylinder **5**, having a distal end **10** and a proximal end **15**. Exiting from proximal end **15** are one or more advancement/retraction control elements **20**, which are connected to the ligation subassembly (not shown in FIG. **1**) disposed inside cylinder **5**. In the construction shown in FIG. **1**, advancement/retraction control elements **20** comprise cables or wires. One or more advancement/retraction control elements **20** are used to advance or withdraw the ligation subassembly (not shown in FIG. **1**) disposed inside cylinder **5**. In addition to the foregoing, one or more constriction control elements **25** also exit from the proximal end of cylinder **5**. Constriction control elements **25** are also connected to the ligation subassembly (not shown in FIG. **1**) disposed inside cylinder **5** and are used to tighten or loosen the ligating element (also not shown in FIG. **1**) about a portion of the tissue or the like. In the construction shown in FIG. **1**, constriction control elements **25** comprise cables or sutures.

Looking next at FIG. **2**, outer cylinder **5** is shown in phantom. FIG. **2** shows the ligation subassembly **30** in an undeployed state, i.e., with ligation subassembly **30** retracted into cylinder **5**. Inside cylinder **5**, ligation subassembly **30** is shown having a ligating element **32** (e.g., a suture or string) that may be connected to supports or guides (such as felt pledgets or loops **35**) which help to grip and protect the tissue which is being ligated. Ligation subassembly **30** also includes supporting structure **40** with struts **45**. Felt pledgets **35** are disposed on the distal ends of struts **45**. Struts **45** are configured to expand when ligation subassembly **30** is deployed from cylinder **5**. In one preferred construction, struts **45** are expanded by connecting them to one another with springs **50**, whereby to render struts **45** self-expandable when the struts are advanced out of the distal end of cylinder **5**. Ligation subassembly **30** is connected to advancement/retraction control elements **20**, whereby the ligation subassembly **30** can be advanced out of, or retracted into, cylinder **5**. Furthermore, ligation subassembly **30** is connected to constriction control elements **25**, whereby the ligating element **32** can be constricted about a piece of tissue or the like. Advancement/retraction control elements **20**, and/or constriction control elements **25**, may be connected to an appropriate handle (not shown) for manipulation by a practitioner.

Looking now at FIG. **3**, there is shown the distal end **10** of cylinder **5**, with the ligation subassembly **30** undeployed within outer cylinder **5**, with felt pledgets **35**.

Looking next at FIG. **4**, a portion of the ligation subassembly **30** is shown advanced out the distal end of the cylinder **5**. The ligation subassembly **30** expands as the struts **45** exit the constraining environment of tube **5** and expand away from one another. In the construction shown in FIGS. **1-4**, struts **45** expand under the influence of springs **50**. Ligation subassembly **30** is connected to constriction control elements **25** which extend beyond proximal end **15** of tube **5** for actuation by the

practitioner. Ligation subassembly **30** may be advanced out of the cylinder by pushing on advancement/retraction control elements **20**.

FIG. **5** is similar to FIG. **4**, except that the walls of cylinder **5** are shown in phantom, thereby exposing the inner workings of the device. Struts **45** are shown connected to supporting structure **40**, e.g., an inner supporting ring **40**.

FIG. **6** is a distal end view of the device, showing ligation subassembly **30** advanced out of cylinder **5**. Ligation subassembly **30** is expanded radially, with the ligating element **32** following an expanded arcuate path about the distal ends of struts **45**, with the proximal ends of ligating element **32** passing up through the center of cylinder **5** for actuation by constriction control elements **25**. Thus, ligating element **32** is supported by struts **45** (or other means), struts **45** may be expanded by springs **50** (or by other means), and struts **45** may be supported by supporting structure **40**.

Looking next at FIG. **7**, ligating catheter **2** is shown with ligating element **32** contracted. Ligating element **32** may be contracted by pulling on the proximal ends of constriction control elements **25**. This actuation causes radial contraction of the ligature loop.

FIG. **8** is a distal end view of the ligating catheter **2** with ligating element **32** contracted. There is radial compression of the ligature loop. Preferably, the inner supporting structure **40** remains unchanged in radial dimension, as does the distal end of the cylinder **5**. Preferably, struts **45** and springs **50** collapse as the device is actuated by the practitioner.

FIG. **9** shows struts **45** and springs **50** retracted back into cylinder **5**, i.e., by pulling on the advancement/retraction control elements **20**. Ligating element **32** remains in place, applying radial compression to any captivated tissue.

FIG. **10** is similar to FIG. **9**, except that ligating catheter **2** is shown with its cylinder **5** in phantom. Struts **45**, springs **50**, and supporting structure **40** are shown retracted into cylinder **5**.

FIG. **11** shows the ligating element **32** severed from constriction control elements **25**.

Guide Catheter

FIG. **12** shows the ligating catheter **2** equipped with an alignment element **90**. Alignment element **90** is intended for use in aligning ligating catheter **2** with a left atrial appendage or other target structure. In one embodiment of the present invention, alignment element **90** comprises a radio-opaque material and the device is placed into the desired anatomical position by visualization, e.g., fluoroscopy.

Alternatively, and more preferably, alignment element **90** is intended to work in conjunction with a guide catheter **100**, wherein the guide catheter **100** is placed (e.g., endoluminally) within the interior of the left atrial appendage. In this construction, guide catheter **100** also comprises a radio-opaque material, and alignment element **90** and guide catheter **100** are placed in alignment by visualization.

Even more preferably, ligating catheter **2** and guide catheter **100** are provided with physical means (e.g., magnets, male and female connectors, wires and snares, etc.) to facilitate alignment of ligating catheter **2** and guide catheter **100**. Thus, in one preferred construction, ligating catheter **2** has its alignment element **90** equipped with a reference magnet **95** at its distal tip. Guide catheter **100** in turn comprises an alignment element **102** having a reference magnet **105** at its distal tip. More particularly, with this preferred construction, ligating catheter **2** has the alignment element **90** which can be extended from the distal end of cylinder **5**. On the distal end of alignment element **90** is the reference magnet **95**. Alignment element **90** is put into proximity with the guide catheter **100**, which has the alignment element **102** with reference magnet **105** mounted on its distal end. When these two alignment elements **90** and **102** are brought into proximity with one another, magnets **95** and **105** cause the alignment elements **90** and **102** to automatically align with one another.

For example, during left atrial appendage ligation, guide catheter **100** is passed endoluminally into the left atrium appendage under visual guidance such as fluoroscopy or ultrasound. The ligating catheter **2** is passed into the pericardium. The alignment element **90** of the ligating catheter is then extended from cylinder **5**. Once alignment element **90** is placed into proximity with alignment element **102**, magnets **95**, **105** cause the two catheters to automatically align with one another, thereby causing ligating catheter **2** to assume a desired position with respect to the left atrial appendage. Then, ligating catheter **2** is utilized as described above to ligate the left atrial appendage.

Looking next at FIG. **13**, there is shown a guide catheter **100** which is provided with an expandable element **115**. Expandable element **115** is adapted to expand inside the anatomy (e.g., the left atrial appendage) so as to facilitate ligation. As noted above, guide catheter **100** has a magnet **105** mounted to its distal end. It should be noted that expandable element **115** is shown in its non-expanded state in FIG. **13**.

Looking next at FIG. **14**, guide catheter **100** is shown with its expandable element **115** in its expanded state.

FIG. **15** shows guide catheter **100**, with its expandable element **115** not expanded, and with guide catheter **100** disposed in the left atrial appendage **130**.

FIG. **16** shows guide catheter **100**, with its expandable element **115** expanded, and with guide catheter **100** shown in the left atrial appendage **130**. In this respect it should be appreciated when expandable element **115** is in its expanded condition within left atrial appendage **130**, expandable element **115** may or may not alter the shape of the recipient tissue, depending on the size of the tissue cavity, the size of the expanded expandable element **115**, etc.

Ligating Catheter Used in Conjunction with Guide Catheter

FIG. **17** shows guide catheter **100** with its expandable element **115** expanded in the left atrial appendage **130**, and with ligating catheter **2** expanded over the left atrial appendage **130**. This aligned positioning is facilitated through the use of alignment element **90** on ligating catheter **2** and alignment element **102** on guide catheter **100**. More particularly, guide catheter **100** is positioned in the left atrial appendage **130**, expandable element **115** is expanded, ligating catheter **2** is positioned in the state depicted in FIGS. **4**, **5** and **6** and, using guide elements **90** and **102** to align the apparatus, ligating catheter **2** is slid over the left atrial appendage **130**. Guide catheter **100** (inside the left atrial appendage) and ligating catheter **2** are aligned in this preferred construction using magnets **120** and **95**, respectively. Significantly, by properly sizing the apparatus vis-à-vis the anatomy, ligating element **32** can be positioned at the neck of the left atrial appendage (and on the atrium side of expandable element **115**) when alignment elements **90** and **102** function as described.

Looking next at FIG. **18**, guide catheter **100** is shown in the left atrial appendage **130**, with its expandable element **115** in its expanded condition, and ligating catheter **2** is shown actuated as described hereinabove with respect to FIGS. **7** and **8**. Due to the relative positioning of the expanded guide catheter **100** within the left atrial appendage **130** while ligating cath-

eter **2** is being actuated, the constricting ligating element **32** is maintained at the neck of the left atrial appendage **130** by the presence of the expandable element **115**, thereby helping to ensure proper positioning of the ligating element **32** relative to the anatomy. In other words, the presence of the expandable element **115** inside the left atrial appendage **130** guides ligature **32** into the desired position **135**. In the example of ligating the left atrial appendage **130**, the desired position **135** is where the left atrial appendage **130** meets the left atrium **140**.

Looking next at FIG. **19**, the apparatus is shown with guide catheter **100** still in the left atrial appendage **130**, but with the ligating catheter **2** withdrawn, leaving the ligating element **32** deployed at the neck of the left atrial appendage **130**.

In FIG. **20**, guide catheter **100** has had its expandable element **115** returned to its unexpanded condition.

Looking next at FIG. **21**, the left atrial appendage **130** is shown with guide catheter **100** removed from the interior of the left atrial appendage, leaving ligating element **32** at the location where the left atrial appendage **130** meets the left atrium **140**, thereby effectively ligating the left atrial appendage from atrium **140**.

One Preferred Form of Use

In one preferred form of use, guide catheter **100** is passed endoluminally across the atrial septum and into the left atrium. Guide catheter **100** (FIG. **22**) has one or more magnets **105** at its tip. Magnets **105** are preferably so-called "rare earth" magnets composed of, for example, Neodymium-Iron-Boron, Cobalt-Samarium or other powerful fixed magnet elements. Just behind the magnets, preferably integral with and axi-symmetric to the body of the guide catheter, is inflatable balloon **115** (FIG. **23**) which, when inflated, is spherical, conical, elliptical or of other configuration, and which preferably conforms roughly to the size and shape of the left atrial appendage **130**. The entire guide catheter **100**, inclusive of balloon **115** and magnets **105**, is of a size consistent with passage through a commercially-available sheath (not shown), the likes of which may be readily passed across the atrial septum under fluoroscopic guidance using currently available tools and techniques.

In one preferred use of this system, the practitioner gains percutaneous access to the femoral vein using the Seldinger or other standard technique, and the aforementioned sheath (not shown) is introduced under fluoroscopic guidance across the atrial septum. The magnetic tip **105** of the guide catheter is then advanced out of the aforementioned sheath and into the left atrial appendage, in the manner previously discussed.

The second instrument used with this iteration (i.e., the ligating catheter **2**, as shown in FIG. **24**) is introduced into the pericardial space, between the heart and the pericardium. Pericardial access may be obtained, for example, by either a small incision below the zyphoid process of the sternum, or by percutaneous access using needles or dedicated systems designed for such purposes. Under fluoroscopic guidance, a wire is introduced into the pericardial space, between the heart and the pericardial sack. Similarly, pericardial access can be obtained by way of a mini-thoracotomy or by a "Chamberlain"-type incision over the 2nd costal cartilage. Percutaneous access using dedicated systems designed for such purposes is generally preferred as it can be done under local anesthesia. An incision over the 2nd costal cartilage, or a small incision below the zyphoid, is generally preferred to approaches that require violation of the left pleural space.

Once pericardial access is obtained, the second instrument (i.e., the ligating catheter **2**, as shown in FIG. **25**) is introduced to the surgical site. In a preferred embodiment, the second instrument is preceded by a series of dilators and sheaths that are introduced over wires. The dilators are of a progressively increasing size culminating in the placement of a large thin-walled tube or cylinder **5**, approximately 24 French or smaller, positioned such that its distal end is in the region of the left atrial appendage. This thin-walled tube **5** then acts as a delivery cannula for advancing the ligating subassembly **30** to the surgical site. In one iteration, the distal end **10** of the thin-walled tube **5** is deflectable by an asymmetric element that can be placed under tension. Alternatively, the thin-walled tube may have a permanent angulation or curve at its tip.

Once the thin-walled tube **5** is in position, the intrapericardial tool (i.e., the ligating subassembly **30**) is advanced down the thin-walled tube **5**. In a preferred embodiment, the ligating catheter **2** comprises a central intrapericardial catheter or alignment element **90** at the end of which is one or more rare-earth magnets **95**, as described previously. These magnets **95** are poled to attract the ligating catheter **2** to the guide catheter **100** (previously placed in the left atrial appendage) in an end-to-end orientation. The ligating catheter **2** may be flexible or, in another embodiment, is stiff with a malleable, deflectable tip.

Coaxial to this alignment element **90**, and constructed in such a manner that it can be advanced or withdrawn relative to either the alignment element **90** or the thin-walled tube **5**, is a tube **150** that ends in a funnel-like or trumpet-bell flare **160**. The internal diameter of this flared tube **150** is significantly larger than the external diameter of the intrapericardial magnet-tipped alignment element **90** (over which the flared tube **150** slides) so as to allow vacuum to be conveyed from the back of the flared tube **150** to the distal flare **160**. This flared end **160** acts as a suction cup to grasp the tip of the left atrial appendage **130** from outside the heart.

In a preferred embodiment, the ligating catheter's alignment element **90** is advanced (FIG. **26**) under fluoroscopic guidance until it engages, and couples with, the guide catheter **100** (FIG. **27**), which was previously placed across the atrial septum and into the inside of the left atrial appendage. Once such alignment has been achieved, and magnetic coupling confirmed by fluoroscopy, the flared tube **150** is advanced (FIG. **28**) until it comes into contact with the outside of the left atrial appendage. Suction is then applied to the back of the flared tube **150**, such that the left atrial appendage is fixed to the tip of the flared tube by vacuum.

Over the outside of this flared tube **150**, but inside the lumen of the 24 French thin-walled tube **5**, is a Nitinol stent-like structure or ligation subassembly **30** that can be advanced down the thin-walled tube **5** toward the tissue by way of a stiff catheter or other structure (i.e., the advancement/retraction control element **20**) attached to its back end. This Nitinol structure **30** is designed to expand (once released from the constraints of the thin-walled outer tube **5**) into a bell shaped crown (FIG. **29**), the tips of which attach (circumferentially) the loop of a snare (i.e., the ligating element **32**). In a preferred embodiment, the ligating element or snare **32** is composed of polypropylene or PTFE suture. The snare loop **32** is secured to the tips of the crown **30** in a reversible, easy-to-release fashion.

Once the left atrial appendage is secured with suction, the Nitinol structure **30**, and its attached snare **32**, is advanced over the flared tube **150** toward the left atrial appendage. The flared tube **150** extends 2 or 3 centimeters beyond the end of the thin-walled outer tube **5**. As such, the Nitinol structure **30**

begins to expand into a bell-shape which facilitates its advancement over the flared suction catheter **150**, and over the left atrial appendage.

Once the Nitinol structure **30** has been advanced to the point where it is near the base of the left atrial appendage, the balloon **115** on the guide catheter **100** inside the appendage is inflated, preferably with a contrast material. The Nitinol structure is advanced under fluoroscopic guidance so that the tips of its bell-shaped crown **30** (and the suture snare **32**) are beyond the inter-atrial balloon (FIG. **30**). The snare **32** is then tightened by pulling on a strand of the suture that runs down the lumen of the stiff catheter **20** which is used to advance the Nitinol structure **30** (FIG. **31**). With the suture snared, the guide catheter's balloon is deflated and the trans-septal left atrial catheter **100** is removed. The suture snare **32** is then preferably tightened again to account for the space previously occupied by the inter-atrial catheter **100**. The Nitinol structure **30** releases away from the suture snare **32** when the snare is tightened. The ligating catheter **2** is then removed and the suture is cut at the skin.

Additional Constructions

In a preferred form of the present invention, and looking now at FIG. **32**, a wire **155** is passed through the left atrial appendage **130**, through the wall of the left atrial appendage **130** and advanced through the pericardial space, whereby tip **165** of the left atrial appendage is perforated. Wire **155** can then be grasped by a catheter or snare in the pericardial space and pulled all the way through the pericardium and then out of the body, thereby creating a single wire track on which guide catheter **100**, ligating catheter **2**, and/or other devices can be passed along from either end of wire **155**. With this construction, alignment element **90** on ligating catheter **2**, and/or alignment element **102** on guide catheter **100** may be omitted if desired. Furthermore, with this embodiment of the invention, guide catheter **100** may be omitted altogether if desired.

Additionally, if desired one or more of the magnets **95** and/or **105** may comprise an electromagnet. Such a construction permits the magnetic field to be selectively turned on and off, thus facilitating separation of the devices at the end of the procedure.

Furthermore, in the foregoing description, struts **45** are described as being preferably expanded by connecting them to one another with springs **50**, whereby to render the struts self-expandable when they are advanced out of the distal end of cylinder **5**. Alternatively, struts **45** may be expanded by other means, e.g., an expansion mechanism mounted to struts **45**, or by making struts **45** out of a spring material (e.g., a superelastic material such as Nitinol), etc.

Addition Aspects of the Present Invention

In one preferred form of the invention, the novel apparatus and method uniquely combine two or more of the following components:

(1) an elongated element such as a cylinder;

(2) an expandable element to help place the ligature over the tissue to be ligated;

(3) the ligature;

(4) an alignment mechanism; and

(5) an expandable element that helps guide the ligature into its proper position as the ligature is deployed.

In one aspect of the invention, an alignment system is provided for positioning a ligature delivery apparatus at a desired location around a tissue structure such as the left atrial appendage.

In another aspect of the invention, a tissue expander is provided for positioning a ligature at a desired location around a tissue structure such as the left atrial appendage.

And in another aspect of the invention, a radially-adjustable ligature delivery apparatus is provided for positioning a ligature at a desired location around a tissue structure such as the left atrial appendage. This delivery apparatus may be expandable.

In still another aspect of the invention, there is provided a ligature system which includes an alignment system, a tissue expander, and a radially-adjustable ligature delivery apparatus, and which is configured to position a ligature around a tissue structure such as a left atrial appendage.

And in still another aspect of the invention, there is provided a ligature system configured to position a ligature around a tissue structure such as the left atrial appendage without opening the chest.

And in still another aspect of the invention, there is provided a ligature system configured to position a ligature around a tissue structure such as the left atrial appendage without opening the chest, using at least two catheters entering the body from remote locations such as a vein, artery and/or through the skin.

In another aspect of the invention, there is provided a novel system comprising a guide member configured for placement within the left atrial appendage of a patient and adapted to provide a reference for positioning a ligature at a desired location around the left atrial appendage.

In yet another aspect of the invention, there is provided a ligature delivery apparatus having an alignment component configured for positioning a ligature at a desired location in response to the reference of the aforementioned guide member disposed within the left atrial appendage.

In still another aspect of the invention, there is provided a tissue expander configured for placement within the left atrial appendage and adapted to define a desired location for positioning a ligature.

In still another aspect of the invention, there is provided a reference catheter having both a guide member and a tissue expander for placement within the left atrial appendage.

In still another aspect of the invention, there is provided a radically-adjustable ligature delivery apparatus configured for placing a ligature at a desired location around the left atrial appendage of a patient.

In still another aspect of the invention, there is provided a delivery catheter having both an alignment component corresponding to the aforementioned guide member within the left atrial appendage of a patient and an adjustable ligature delivery apparatus for placing the ligature therearound.

In still another aspect of the invention, there is provided a delivery catheter having both an alignment component corresponding to the aforementioned guide member within the left atrial appendage of a patient and an adjustable ligature delivery apparatus for placing the ligature therearound, whereby the delivery apparatus contains an expandable element.

In still another aspect of the invention, there is provided a ligature system including both a reference catheter and an alignment catheter configured to correspond with one another so as to place a ligature at a desired location around the left atrial appendage of a patient.

In still another aspect of the invention, there is provided a ligature system including both a reference catheter and an alignment catheter configured to correspond with one another so as to place a ligature at a desired location around the left

atrial appendage of a patient, in which either the reference catheter or the alignment catheter, or both, include an expandable element.

In another aspect of the invention, a device incorporating one or more of the above-identified components is placed in proximity to the tissue which is to be ligated. This can be done in many ways such as under direct visualization or under fluoroscopic, ultrasound, radiographic, CT, MRI, etc., guidance. Additionally, it can be further aligned by using such devices as alignment strands, magnets, etc.

And in another aspect of the invention, the apparatus and method may be used to ligate the left atrial appendage as follows. Access to the pericardial space is acquired using standard techniques such as the Seldinger over-the-wire technique. For example, such device, which preferably comprises an elongated device such as a cylinder containing an expandable element, a ligature, and an alignment mechanism, is placed into the pericardium over a guidewire. For example, the elongated device can be a large catheter in which there is an expandable element, a ligature, and an alignment mechanism.

And in another aspect of the invention, a guide catheter is placed into the left atrium using standard techniques, such as transseptally, through the veins or retrograde across the mitral valve, etc. The guide catheter in the left atrium is then placed into the left atrial appendage under fluoroscopic guidance. At this point, the guide catheter is in the left atrial appendage and the ligating mechanism is disposed in connection with a deployment catheter in the pericardial space. The guide catheter in the left atrium and the deployment catheter in the pericardial space are then aligned with one another. This can be done using a variety of techniques. For example, one or both of the devices can be magnetized, thus allowing them to be aligned relative to one another using magnetic force. Alternatively, the guide catheter and deployment catheter can be "steered" into proximity using visual or ultrasonic guidance. Or the guide catheter in the left atrium can penetrate the left atrial appendage and be "snared" by the deployment catheter in the pericardium. At this point, the device in the pericardium is advanced into proximity with the left atrial appendage. A ligating apparatus is then deployed from the deployment catheter and advanced over the left atrial appendage. Preferably, the guide catheter inside the left atrium includes an expandable element such as a balloon. This expandable element is then expanded inside the left atrial appendage. In so doing, this expansion helps prevent the ligature from slipping or migrating off of the left atrial appendage as the ligature is tightened around the left atrial appendage. The ligature is then tightened around the left atrial appendage. The expandable element inside the left atrium is then contracted. The guide catheter inside the left atrial appendage is then backed out of the left atrial appendage. The procedure can be repeated as necessary. The guide catheter and deployment catheter are then removed from the body cavity.

Alternatively, the guide catheter inside the left atrial appendage may be removed after the ligature has been mostly placed, but before the final tightening of the ligature. This will allow the base of the left atrial appendage to be completely occluded after the guide catheter is withdrawn from the left atrial appendage.

The following text further illustrates a preferred manner for ligating the left atrial appendage. A trans-septal left atrial guide catheter that has (integral to its construction) a rare-earth magnet, or other alignment means, and an inflatable balloon, is of great utility in effectively occluding the left atrial appendage with a snare or ligature. The left atrial appendage is typically roughly conical in shape, with a slight neck or narrowing in the plane of the orifice where it joins the left atrium proper. To effectively exclude the left atrial appendage from the outside with a ligature or snare, the snare must be tightened precisely in this plane. Ideally, with the ligature tightened, the resultant left atrial geometry should be essentially spherical, with only a slight dimple visible from the endocardial or luminal aspect at the site of the obliterated orifice. If the snare is tightened above the plane of the orifice (toward the left atrial appendage tip), incomplete exclusion of the left atrial appendage may result in a persistent diverticulum of left atrial appendage, which may provide a site of stasis and thrombus formation in the fibrillating atrium. Conversely, if the snare is tightened below the plane of the orifice, there is a risk of injury to the circumflex coronary artery, which runs in the atrio-ventricular grove.

Snaring the left atrial appendage precisely and accurately in the optimal plane presents several technical challenges. In some individuals, the geometry of the left atrium and left atrial appendage may be such that the neck or narrowing between them is poorly defined, especially from the epicardial or outer aspect. Furthermore, because the left atrial appendage wall is thin and flexible, and the wall tension low (left atrial pressure is generally low, e.g., <20 mm Hg), the external geometry of the left atrial appendage-left atrial junction may be of little help in constraining the snare to the correct plane during tightening. This challenge is compounded by the fact that the anatomy is moving vigorously, even in the fibrillating atrium, due to translational motion from ventricular systole. A trans-septal left atrial guide catheter equipped with a magnetic tip and a large inflatable balloon such as described above enables snaring the left atrial appendage in the proper plane. More particularly, it is believed that identifying and capturing the tip of the left atrial appendage using just an intra-pericardial instrument under fluoroscopic or echocardiographic guidance may prove prohibitively challenging. At the same time, passing a catheter across the atrial septum into the left atrium, and subsequently positioning it in the apex of the left atrial appendage, is readily accomplished by those skilled in the art with catheters that are commercially available. Thus, positioning a guide catheter with a rare-earth magnet (or other alignment mechanism) at the tip thereof in the left atrial appendage is readily achievable and thereby allows fluoroscopic guidance as to the position of the left atrial appendage apex, as well as enabling precise capturing of the apex with an intra-pericardial tool.

A balloon near the tip of the trans-septal left atrial guide catheter greatly facilitates positioning and tightening of the snare or ligature in the proper plane of the orifice between the left atrial appendage and left atrium. Preferably, the balloon is designed to inflate to approximately the size of the left atrial appendage. As the balloon is inflated, it is confined to the left atrial appendage by the neck or narrowing at the orifice between left atrial appendage and left atrium. This may be readily confirmed by echocardiographic examination, or fluoroscopy, especially if the balloon is inflated with a contrast agent. Separate ports in the guide catheter allow the contrast agent to be injected into the left atrial appendage and/or the left atrium proper to provide further confirmation of correct position of the inflated balloon.

The inflated balloon accentuates external geometric features at the left atrial appendage-left atrial junction. When the spherical balloon is inflated, the flexible left atrial appendage is distended and its shape changed (e.g., to spherical) to facilitate ligation. The junction between the left atrial appendage and left atrium becomes better defined, like a waist of a snowman. This constrains the snare or ligature to the proper plane during tightening. The balloon, and consequently the

left atrial appendage, is inflated to a pressure significantly higher than that of the left atrium proper. As such, there is a significant differential in wall tension between the left atrial appendage and the left atrium. As the balloon is spherical, an attempt at snaring above the plane will result in the snare slipping off of the tense spherical surface toward the low tension, flexible neck. Radio-opaque contrast agent in the balloon, the ability to selectively inject contrast in the left atrial appendage and/or left atrium proper, and a radio-opaque snare or ligature greatly facilitate performing these procedures under fluoroscopic guidance. Once the left atrial appendage-left atrial junction is snared, the balloon is deflated and removed and the snare tightened completely.

In general, it should be appreciated that, among other things, the invention comprises the alignment of two devices, one within and one outside of a lumen, cardiac chamber, etc. Thus, the present invention could be used in the stomach to help with an endoscopic fundiplication.

The foregoing description is intended to illustrate preferred embodiments of the present invention. However, numerous changes may be made to the preferred embodiments without departing from the scope of the present invention. Thus, one or more of the steps of the method, and/or one or more of the components of the apparatus, may be modified or omitted. Also, the present apparatus and method may be used to ligate any tissue or like structure in the body.

What is claimed is:

1. A kit comprising:

first and second alignment members, wherein the first and second alignment members are configured to align with one another, wherein the second alignment member has a size and a length adapted for accessing the pericardial space and the first member has a size and a length adapted for accessing the left atrial appendage through the vasculature, and wherein the first alignment member comprises a guidewire and a guide catheter comprising a lumen and a balloon, and wherein the guidewire is slidably positioned through the lumen of the guide catheter; and

a closure device comprising an elongate body comprising a lumen therethrough, a suture loop releasably attached to an expandable structure moveable between a first low-profile configuration and a second expanded configuration, wherein the expandable structure is at least partially within the lumen in the first low-profile configuration and wherein advancement of the expandable structure to the second expanded configuration holds the suture loop in a configuration for placement around the left atrial appendage, and wherein the second alignment member is slidably positioned through the lumen of the elongate body.

2. The kit of claim **1**, wherein the first and second alignment members comprise magnets.

3. The kit of claim **1**, wherein the first and second alignment members comprise electromagnets.

4. The kit of claim **1**, wherein the guide catheter is attached to the first alignment member.

5. The kit of claim **1**, wherein the closure device comprises a delivery catheter.

6. The kit of claim **5**, wherein the expandable structure is bell-shaped when expanded.

7. The kit of claim **5**, wherein the expandable structure is self-expandable.

8. The kit of claim **5**, wherein the expandable structure comprises expandable arms.

9. The kit of claim **8**, wherein the expandable arms comprise springs.

10. The kit of claim **1**, wherein the suture loop comprises polypropylene or PTFE.

11. The kit of claim **1**, wherein the closure device comprises a suction tube.

12. The kit of claim **1**, wherein the first and second alignment members comprise radio-opaque materials.

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